Health Technology Assessment

Pediatric Bariatric Surgery

Bariatric Surgery for morbid obesity in Pediatric Patients

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Presented by:

ECRI Institute
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Bariatric Surgery for Morbid Obesity in Pediatric Patients

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Bariatric Surgery for Morbid Obesity in Pediatric Patients

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Executive Summary

Among pediatric patients, the prevalence of obesity nearly tripled between 1970 and 1999. Data from the National Health and Nutrition Examination Survey in 1999-2002 suggest that 16% of patients aged 6-19 would be classified as overweight by the U.S. Centers for Disease Control and Prevention. The medical risks of obesity in pediatric patients include type 2 diabetes, hypertension, coronary artery disease, stroke, gallbladder disease, musculoskeletal problems, asthma, and gastroesophageal reflux disease (GERD). Pediatric obesity may be particularly associated with quality-of-life limitations and social marginalization.

Bariatric surgery is major surgery in which a surgeon alters the patient's digestive tract in an attempt to induce weight loss, improve medical comorbidities, enhance quality of life, and (ultimately) extend survival. Many different types of bariatric surgical procedures are performed, so "bariatric surgery" cannot be considered a single procedure. Some bariatric surgeries are purely restrictive—they cause weight loss by limiting the amount of food that can be consumed in one meal. Others are malabsorptive—they cause weight loss by reducing the amount of food that is absorbed into the body. The two most common bariatric surgical procedures are laparoscopic adjustable gastric banding (LAGB), which is a purely restrictive procedure, and Roux-en-Y gastric bypass (RYGB), which is both restrictive and malabsorptive.

This systematic review summarizes the evidence on bariatric surgery in the treatment of pediatric patients with morbid obesity. Several unique concerns have been raised about bariatric surgery in this population, including questions about informed consent, physical growth, and compliance. Critical questions involve weight loss as compared to non-operative treatment, improvement of medical comorbidities and quality of life, adverse events experienced by surgical pediatric patients, the operative and long-term postoperative costs of surgery, and whether any patient characteristics are associated with surgical outcomes.

Overall, we examined the data from 16 published studies that enrolled a total of 494 pediatric patients. Seven studies reported outcomes after LAGB, five studies reported outcomes after RYGB, two studies reported outcomes after vertical banded gastroplasty (VBG), one study reported outcomes separate for two procedures, RYGB and VBG, and one study reported outcomes after a combined VBG-RYGB procedure. Below, the five clinical questions are listed, along with the conclusions we drew based on the evidence.

1. Does pediatric bariatric surgery lead to sustained and clinically significant weight loss compared to non-operative approaches?
    a. In patients aged 21 or less
    b. Specifically in patients aged 18-21
    c. Specifically in patients aged 13-17
    d. Specifically in patients aged 12 or less

ECRI Institute evidence assessments:

- Laparoscopic Adjustable Gastric Banding (LAGB) for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches. Strength of evidence: Moderate.

- Roux-en-Y Gastric Bypass (RYGB) for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches. Strength of evidence: Moderate to Weak.

- The evidence is insufficient to permit quantitative estimates of the precise amount of weight loss after any bariatric surgical procedure for pediatric patients.

- The evidence is insufficient to permit any conclusions about weight loss after other bariatric surgical procedures for pediatric patients.

- The evidence is insufficient to permit any conclusions about weight loss in specific age subgroups (18-21, 13-17, 12 or less) within the pediatric population.

Prior to surgery, pediatric patients had undergone multiple unsuccessful attempts at weight loss using non-surgical approaches (e.g., diets). Such attempts are a standard pre-requisite prior to bariatric surgery. Thus, our primary analysis assumed that patients would not have lost weight without surgery.

Five of seven LAGB studies reported weight or BMI data that met inclusion criteria; the length of followup ranged from 1.7 to 3.3 years. Our study quality assessments indicated that four studies were of Moderate quality, and one study was of Low quality. Our random-effects meta-analysis indicated statistically and clinically significant weight loss after surgery. We performed six tests to confirm the robustness of the finding, including an alternate assumption that patients might lose as many as 1.3 BMI units without surgery (change in weight as measured by kilograms per meter of height squared). All analyses still indicated clinically significant weight loss. Based on the overall moderate quality of the studies, we rated the strength of the evidence as Moderate.

Five of six RYGB studies reported weight or BMI data that met inclusion criteria; the length of followup ranged from 1 to 6.3 years. Our study quality assessments indicated that two studies were of Moderate quality, and three studies were of Low quality. Our random-effects meta-analysis indicated statistically and clinically significant weight loss after surgery, and this analysis also passed our six robustness tests. Based on the overall low quality of the studies, we rated the strength of the evidence as Weak. Three of the RYGB studies had also reported weight loss specifically at one year after surgery; these three studies were of overall Moderate quality. A meta-analysis of the one-year BMI data again indicated clinically significant weight loss, and we rated the strength of this evidence base as Moderate.

The evidence did not permit precise quantitative estimates of the amount of BMI units lost after either LAGB or RYGB, because studies did not generally report sufficient information for us to calculate the pre-post correlation for BMI. Also, the evidence on weight loss after other bariatric procedures (e.g., VBG) did not support conclusions due to low quantity and

quality of evidence. For specific age groups of pediatric patients (e.g., 13-17), there were not enough studies of any single age group to permit conclusions.

2. Does bariatric surgery for patients a-d (as above) improve co-morbid conditions linked to obesity (e.g., diabetes, hypertension, obstructive sleep apnea, musculoskeletal disorders), quality of life, or survival, as compared to non-operative approaches?

ECRI Institute evidence assessments:

- Laparoscopic Adjustable Gastric Banding (LAGB) for morbidly obese patients aged 21 or less does resolve co-morbid conditions linked to obesity (hypertension, dyslipidemia, asthma) compared to non-operative approaches. Strength of evidence: Weak.

- Roux-en-Y Gastric Bypass for morbidly obese patients aged 21 or less does resolve co-morbid conditions linked to obesity (hypertension, sleep apnea) compared to non-operative approaches. Strength of evidence: Weak.

- The evidence is insufficient to permit quantitative estimates of the likelihood of comorbidity resolution, quality of life improvement, or survival after any bariatric surgical procedure for pediatric patients.

- The evidence is insufficient to permit any conclusions about comorbidity resolution after other bariatric surgical procedures for pediatric patients.

- The evidence is insufficient to permit any conclusions about comorbidity resolution in specific age subgroups (18-21, 13-17, 12 or less) within the pediatric population.

Three of seven LAGB studies met inclusion criteria for comorbidity and quality of life outcomes. For each of three comorbidities (hypertension, dyslipidemia, and asthma), data were reported by two of the three studies. Resolution rates were 50%-100% for hypertension, 67%-100% for dyslipidemia, and 100% for asthma. These are large reductions, but due to the moderate quality and limited quantity, we rated the strength of evidence as Weak for these outcomes.

Four of six RYGB studies reported comorbidity data that met inclusion criteria. Three of the four studies reported hypertension resolution (with resolution rates ranging from 50% to 100%) and two of the four studies reported resolution of sleep apnea (the rate was 100% in both studies). Again, these are large reductions, but due to the moderate quality and limited quantity, we rated the strength of evidence as Weak for these outcomes.

For other comorbidities (diabetes, GERD, musculoskeletal problems) and for quality of life, there was only one study of any specific bariatric procedure with included data, so the evidence was insufficient to permit conclusions. Similarly, we drew no conclusions about other bariatric procedures or specific age groups, due to a limited quantity of evidence.

3. What are the relative safety profiles of bariatric surgery and non-operative approaches for patients a-d (as above)?

ECRI Institute evidence assessments:

- The strength of the evidence for adverse events was Moderate.
- No perioperative mortality was reported across included studies.
- One late death was reported in a RYGB study; no late death was reported in other included studies.
- The overall reoperation rate for the LAGB cases was 9.39%; such reoperation rate was not available for the RYGB cases.
- The most frequently reported postoperative complication for LAGB was band slippage.
- The most frequently reported postoperative complication for RYGB was problems related to protein-calorie malnutrition and micronutrient deficiency.
- Potentially severe adverse events after RYGB included pulmonary embolism, severe malnutrition, immediate postoperative bleeding, gastrointestinal obstruction, and staple line leak.
- The evidence is insufficient to permit any conclusions about whether bariatric surgery would have any negative impacts on growth and development of pediatric patients.
- The evidence is insufficient to permit any conclusions about potential harms in specific age subgroups (18-21, 13-17, 12 or less) within the pediatric population.
- Systematic reviews on pediatric obesity management did not provide sufficient data for the development of a safety profile of nonoperative approaches.

All 16 studies were included for data on adverse events. The low patient enrollment, however, meant that we did not attempt to estimate the rate of any adverse event. For LAGB, the primary concern is the need for reoperation, which was necessary for 26 pediatric patients (9.4%). Reasons for reoperation include band slippage, intragastric migration, and port/tubing problems. For RYGB, there is a different profile of adverse events, varying from mild events (e.g., slight malnutrition, correctable by supplements) to severe events (e.g., pulmonary embolism, severe malnutrition, immediate postoperative bleeding, digestive obstruction, staple line leak). Based on moderate quality, we rated the strength of the evidence for adverse events as Moderate.

4. What are the relative cost profiles of bariatric surgery and non-operative approaches for patients a-d (as above)?

ECRI Institute evidence assessments:

- In 2004, the median hospital inpatient cost for pediatric bariatric surgery was $8,651; the median hospital inpatient charge was $25,021.
- No significant difference in hospital inpatient cost or charge was found between the 13-17 and the 18-21 age groups in 2004. No conclusions can be drawn regarding the cost or charge of patients aged less than 12 due to lack of data.

- We estimated that the total three-year cost of a pediatric LAGB procedure without major postoperative complications is $11,628 in 2007. This total cost contains a cost of $2,793 for postoperative care in the first three years after surgery.

- We estimated that the total three-year cost of a pediatric RYGB procedure (open approach) without major postoperative complications is $14,125 in 2007. This total cost contains a cost of $2,653 for postoperative care in the first three years after surgery.

- Data were not sufficient to permit a comparison of cost between the State of Washington and the nation.

- The evidence was not sufficient to permit the development of a comprehensive cost profile of nonoperative approaches to pediatric obesity management.

Due to the lack of published evidence on the costs of bariatric surgery in pediatric patients with morbid obesity, we conducted our own analyses of publicly available data to estimate hospital inpatient costs, costs of professional services, and postoperative care costs. Based on these analyses, we estimated the overall three-year cost of LAGB without major complications at $11,628 (in 2007 dollars). The corresponding cost for RYGB using an open approach was $14,125.

5. Do the effectiveness, safety and cost of bariatric surgery for patients a-d (as above) vary based on patients characteristics, including:
    a. Chronological age
    b. Physiologic/skeletal age
    c. Pre-surgical BMI
    d. Pre-surgical BMI categories (35-40, 40-50, 50+)
    e. Sex
    f. Race
    g. Co-morbid conditions (e.g., Pickwickian syndrome)
    h. Other factors (e.g., psychosocial or socioeconomic factors)

ECRI Institute evidence assessments:

- The evidence is insufficient to permit any conclusions for this question

Studies' data were included for four of the eight patient characteristics: chronological age (a), pre-surgical BMI (c), pre-surgical BMI category (d), and sex (e). However, none of these associations were addressed by more than two studies of any given bariatric procedure, and the low quantity of evidence precluded conclusions. The association between chronological age and surgical outcome was addressed by only one study of LAGB, one study of RYGB, and one study of combined VBG-RYGB. Similarly, the association between sex and outcome was addressed by only one study each for LAGB, RYGB, and VBG. There were two studies of LAGB addressing the association between pre-surgical BMI and surgical outcome (and also the association between pre-surgical BMI category and surgical outcome), but the overall low quality precluded conclusions.

Introduction

Morbid Obesity in Pediatric Patients

Definitions

Morbid obesity is generally defined as having a body mass index (BMI) of at least 40 kg/m^2 or at least 35 kg/m^2 in the presence of one or more medical comorbidities.(1-3) BMI is computed as the weight in kilograms divided by the height in square meters.

For this report, we defined the "pediatric" population as patients aged 21 or younger, corresponding to the definition of the American Association of Pediatrics.(4) The Centers for Disease Control and Prevention (CDC) have noted that BMI is a "reliable indicator of body fatness in most children and teens".(5) The interpretation of BMI for children and teenagers depends on age and sex, and the CDC definition of an "overweight" pediatric patient is when the BMI is at or above the 95th percentile for that age and sex.(5)

For illustrative purposes, Table 1 shows the CDC weight thresholds for "overweight" in four hypothetical pediatric patients (a 13-year old girl, a 13-year old boy, a 17-year old girl, and a 17 year-old boy). The table also shows the BMIs that correspond to the "overweight" threshold, as well as the weights corresponding to a BMI of 40 kg/m^2. These figures demonstrate that a person with a BMI of 40 kg/m^{2}would weigh much more than a person at the CDC threshold for "overweight".

Body fat is most accurately measured using hydrodensitometry or dual-energy X-ray absorptiometry (DXA),(6) but these methods are highly labor-intensive and costly. BMI, on the other hand, is more feasible because it only requires measurements of height and weight. An important question is whether BMI correlates well with body fatness *in the pediatric population*. Field et al. (2003)(6) addressed this question by measuring both body fat (using DXA) and BMI in 596 children and adolescents. They found that BMI explained 72% of the variance in body fat (corresponding to a Pearson r correlation of 0.85). This finding suggests that in pediatric patients, BMI is a reasonably accurate surrogate for body fatness.

Table 1. Examples of Pediatric Weights and BMIs at Average Height

Age	Sex	Average height[a]	Weight threshold for "overweight"[b]	Actual BMI at that weight	Weight corresponding to a BMI of 40 kg/m^2
13	Girl	5 feet, 1.3 in.	140 pounds	26.2 kg/m^2	214 pounds
13	Boy	5 feet, 0.9 in.	133 pounds	25.2 kg/m^2	211 pounds
17	Girl	5 feet, 3.5 in.	170 pounds	29.6 kg/m^2	229 pounds
17	Boy	5 feet, 8.4 in.	188 pounds	28.2 kg/m^2	266 pounds

a Average heights are based on CDC growth charts.
b "Overweight" is defined by the CDC as a BMI ≥95th percentile for age and sex.

BMI – Body Mass Index
kg – kilograms
in – inches
m – meters

Epidemiology

The prevalence of obesity has increased sharply in recent years. Between 1988 and 1994, 2.9% of adults in the United States were morbidly obese; this percentage rose to 4.9% (10.8 million people) between 1999 and 2002. The condition was more common among women (6.4%) than among men (3.3%). Approximately 26% of U.S. adults had nonmorbid obesity; an additional 34.7% were overweight but not obese.(7,8)

The percentage of adolescents who are severely overweight nearly tripled between 1970 and 1999 (from 5% to 14%).(9) Hedley et al. (2004) used data from the National Health and Nutrition Examination Survey (NHANES) for 1999-2002 to estimate that 16% of pediatric patients aged 6-19 had BMIs above the 95th percentile for age based on CDC growth charts (the study did not report the percentage of pediatric patients who had BMI $\geq$40 kg/m^2).(8)

Health Implications of Obesity

Overweight and obese individuals are at increased risk of type 2 diabetes, hypertension, coronary artery disease, stroke, gallbladder disease (cholelithiasis), osteoarthritis, sleep apnea, respiratory problems, and many types of cancer (including endometrial, breast, prostate, and colon). Obesity is also associated with pregnancy complications, menstrual irregularities, hirsutism, stress incontinence, and psychosocial impairments (e.g., binge eating, altered perception of body image perceptions, depression, social stigmatization).(1,10)

These health risks contribute to obesity-related increases in all-cause mortality. In 2000, about 365,000 deaths in the United States were attributed specifically to poor diet and physical inactivity.(11,12) Approximately seven years of life are lost due to obesity in a 40-year-old white female with a BMI over 45 kg/m^2.(13)

Many studies in pediatric populations have demonstrated the health risks of obesity in pediatric populations.(14-25) Becque(25) determined that 35 of 36 (97%) obese adolescents had four or more serious cardiovascular[1] risk factors. Weiss(22) found that 97 of 195 severely obese adolescents (50%) met criteria for the metabolic syndrome, as compared to 0 of 20 non-obese adolescents. Rhodes(23) studied 14 morbidly obese children and adolescents and found that five of them (36%) had sleep apnea, which was associated with more neurocognitive deficits (learning, memory). Additional risks of obesity among adolescents include musculoskeletal problems, asthma, gastroesophageal reflux disease (GERD), pseudotumor cerebri, gallstones, and menstrual abnormalities.(14,17,24)

Research has also demonstrated reduced quality of life(26) and social marginalization among obese pediatric patients.(27,28) Schwimmer(26) surveyed the quality of life of 106 obese patients aged 5-18, and found an average score of only 67, as compared to 83 for non-obese pediatric patients (on their pediatric QOL scale, 100 indicated excellent quality of life, and 0 indicated extremely poor quality of life). The impact of obesity was persistent for both psychosocial health and physical health. In another study of over 90,000 adolescents in the National Longitudinal Study of Adolescent Health,(27) the authors measured the number of

[1] The factors under consideration were: 1) serum triglyceride >100 mg/dL; 2) HDL cholesterol below the 10th percentile for age and sex; 3) total cholesterol >200 mg/dL; 4) systolic BP above the 90th percentile for age and sex; 5) dystolic BP above the 90th percentile for age and sex; 6) maximal oxygen consumption <24 mL/kg of body weight; and 7) strong immediate family history of cardiovascular disease.

friendship nominations received by other adolescents. The average was lower for overweight adolescents (3.4) than for non-overweight adolescents (4.8). Also, obese adolescents were more likely to receive zero friendship nominations (which was true for 12% of overweight adolescents as compared to 7% of non-overweight adolescents), suggesting social marginalization.

Long-Term Risks

Obese pediatric patients are more likely to become obese adults than their non-obese peers.(18,29-31) In a review of 15 studies, Serdula(29) estimated that 42%-63% of obese school-age children become obese adults; the comparative risk of becoming an obese adult was 4 to 6.5 times higher for obese school-age children than non-obese school-age children. Power(18) used data from a 1958 birth cohort and found similar relative risks of adulthood obesity based on adolescent obesity. Whitaker(30) found that 23 of 30 patients (77%) who had been severely obese at age 15-17 were still obese as adults, and this same percentage (77%) was observed in a study by Freedman(31) that included 186 obese adolescents.

Obesity during adolescence has also been tied directly to health problems in adulthood.(18,31-33) Power(18) reviewed five pertinent studies and found correspondence between adolescent obesity and adulthood all-cause mortality, coronary heart disease, atherosclerosis, colorectal cancer, gout, arthritis, and menstrual problems. Also, Abraham(33) found higher prevalence rates of four medical conditions (diabetes, atherosclerosis, hypertension, and cardiovascular disease) among 19 men whose weight was ≥120% of the average weight for age and height.

Principles and Goals of Treatment

Obesity treatments are intended to promote weight loss, reduce the risks of health problems, improve the quality of life, and (ultimately) extend survival. The categories of treatment include diet, exercise, behavioral modification, pharmacotherapy, and bariatric surgery. Because bariatric surgery is the topic of this assessment, we describe it first, and then we describe non-surgical obesity treatments.

Bariatric Surgery

Bariatric surgery is a specialty area of general surgery devoted to the treatment of obesity. Use of bariatric surgery to treat morbid obesity has increased dramatically in recent years, from approximately 13,000 operations in 1998 to approximately 121,000 operations in 2004.(34)

Pediatric patients (under age 18) comprise about 0.1 - 1% of patients reported to have received bariatric surgery for morbid obesity at various centers.(35-37) Based on our analysis of the Nationwide Inpatient Sample (NIS) of the Healthcare Cost and Utilization Project (HCUP), we estimated that over 2,000 pediatric patients ages 21 and younger in the United States received bariatric surgery in 2004.

Underlying Theory

A wide variety of surgical procedures have been used to treat obesity. Surgeons distinguish between these procedures based on the presence of restrictive or malabsorptive features.(3) Restrictive features are intended to cause weight loss by restricting the amount of food that can be consumed. By contrast, malabsorptive features are intended to cause weight loss by limiting the amount of food that is absorbed by the digestive tract. A procedure can have restrictive features, malabsorptive features, or both.

All bariatric surgical procedures can be performed using either an open or laparoscopic approach. Whereas the open approach involves making a large abdominal incision to enable direct access to the stomach and intestines, the laparoscopic approach utilizes several small incisions, and the operation is performed using specialized instruments and monitors. This less invasive approach is intended to improve short-term operative and perioperative outcomes including blood loss, adverse events, length of hospital stay, and patient recovery time. For a given procedure, however, the open and laparoscopic approaches intend to create the same anatomic structure of the patient's digestive system. The difference lies only in the manner in which the procedure is performed.

Basic Procedure

The two most commonly performed bariatric surgical procedures are laparoscopic adjustable gastric banding (LAGB) and the Roux-en-Y (RYGB) gastric bypass. LAGB is a purely restrictive procedure in which the surgeon places a silicone band around the entire upper portion of the stomach, creating a tiny pouch where food empties from the esophagus to the upper stomach. Because of the tiny pouch and the narrow channel through the band, patients feel satiated after only a small amount of food is eaten. Adjusting the diameter of the band allows more or less food to pass to the lower portion of the stomach. These adjustments permit some flexibility in treatment: the band can be narrowed if weight loss is insufficient, or it can be expanded if the patient experiences severe adverse effects. Two types of bands are currently being used: the LAP-BAND® (Inamed Health, Santa Barbara, CA), and the Swedish Adjustable Gastric Band (SAGB; Ethicon Endo-Surgery, Cincinnati, OH).

The RYGB has both restrictive and malabsorptive features. For restriction, the stomach is partitioned (using staples) into a small upper portion and a large lower portion. Food enters only the upper portion (the gastric pouch). The small intestine is cut 15 to 20 cm distal to the ligament of Treitz. The distal small intestine is connected to the gastric pouch, permitting the emptying of food. This creates one limb (the "Roux," or alimentary limb) of a Y-shaped construction. Creation of the second limb involves connecting the duodenum and upper small intestine to a distal section of the small intestine. The anastomosis is at least 45 cm downstream to prevent reflux of bile and pancreatic juices into the proximal gastric pouch. The two limbs meet and form a common limb at the most distal section of the small intestine, where food and digestive fluids mix.

Other bariatric surgical procedures include vertical banded gastroplasty (VBG), combined RYGB-VBG, and biliopancreatic diversion with duodenal switch (BPD/DS). In VBG, the surgeon creates a small gastric pouch in the upper portion of the stomach using vertically aligned staples. The pouch is drained through a narrow band (stoma) into the rest of the stomach. VBG maintains the anatomic and functional continuity of the gastrointestinal tract; thus, its mechanism of weight loss is purely restrictive. Combined RYGB-VBG, also called the Fobi pouch procedure or the Fobi-Capella procedure, employs the restrictive properties of VBG and the malabsorptive proportions of RYGB. In recent years, the BPD/DS has been used with increasing frequency.(38) This procedure is considered to be more malabsorptive than standard biliopancreatic diversion, and surgeons remove the greater curvature of the stomach. The alimentary limb is created by connecting the distal small intestine to the duodenum distal to the stomach. A second limb (biliopancreatic) permits the emptying of digestive fluids. The two limbs meet in a common channel measuring only 50 to 100 cm, thereby permitting relatively little absorption.

Non-Surgical Treatments for Morbid Obesity

In general, pediatric patients who receive bariatric surgery have previously had unsatisfactory weight loss with non-surgical methods. In this section, we describe non-surgical methods of weight reduction including dietary modification, physical activity, behavioral modification, and pharmacotherapy. Any of these methods can be used simultaneously to optimize weight loss.

Dietary modification can cause weight loss by limiting energy intake below energy expenditure. This modification is individualized per patient based on age, sex, previous calorie intake, and weight-loss goals. Generally, the emphasis in obesity treatment is on limiting overall quantities as well as the intake of fat, sugar, and salt. Further, in the pediatric population, nutrient recommendations differ based on age. The recommended percentage of daily calories for fat, carbohydrates and protein are:(39)

- Fat: 30%-40% for ages 1-3 and 25%-35% for ages 4-18.
- Carbohydrates: 45%-65% for all ages
- Protein: 5%-20% for ages 1-3 and 10%-30% for ages 4-18.

Increasing physical activity and exercise also promote weight loss. Current recommendations vary regarding the amount of necessary exercise in pediatric patients. In 2005, a panel of 13 experts reviewed evidence on exercise and concluded that "school-age youth should participate daily in 60 minutes or more of moderate to vigorous physical activity that is developmentally appropriate, enjoyable, and involves a variety of activities."(40) However, because obese patients are often sedentary before beginning an exercise program, such recommendations only represent a long-term exercise target.

Behavioral modification is also a component of some weight-loss programs.(41,42) This intervention addresses the psychological component of eating and is intended to promote weight loss by helping people make better decisions about eating. Several aspects of behavior are addressed, including when, where, and what to eat and when to stop eating.(41) For example, obese people may be encouraged to avoid certain environments that contribute to weight gain (e.g., fast-food restaurants that serve mostly fatty foods).

Pharmacotherapy employs pharmacologic agents to cause weight loss. These agents may be used in conjunction with diet, exercise, or other weight management programs. Antiobesity agents that have been approved by FDA include orlistat, sibutramine, benzphetamine HCl, diethylpropion HCl, mazindol HCl, phendimetrazine tartrate, and phentermine HCl.(43) These agents affect the noradrenergic pathway or both the noradrenergic pathway and the serotonergic pathway. The only two agents approved for six or more months of use are orlistat and sibutramine. Standard dosing for adolescents is 120 mg three times a day for orlistat, or 5-15 mg/day for sibutramine.(44) However, orlistat is only approved for those aged 12 and older, and sibutramine is only approved for those aged 16 and older. Therefore, some obese pediatric patients do not meet indications for long-term pharmacotherapy.

Methods

Key Questions and Outcomes Assessed

In this report, we address the following five Key Questions:

1. Does pediatric bariatric surgery lead to sustained and clinically significant weight loss compared to non-operative approaches?
    a. In patients aged 21 or less
    b. Specifically in patients aged 18-21
    c. Specifically in patients aged 13-17
    d. Specifically in patients aged 12 or less
2. Does bariatric surgery for patients a-d (as above) improve co-morbid conditions linked to obesity (e.g., diabetes, hypertension, obstructive sleep apnea, musculoskeletal disorders), quality of life, or survival, as compared to non-operative approaches?
3. What are the relative safety profiles of bariatric surgery and non-operative approaches for patients a-d (as above)?
4. What are the relative cost profiles of bariatric surgery and non-operative approaches for patients a-d (as above)?
5. Do the effectiveness, safety and cost of bariatric surgery for patients a-d (as above) vary based on patients characteristics, including:
    a. Chronological age
    b. Physiologic/skeletal age
    c. Pre-surgical BMI
    d. Pre-surgical BMI categories (35-40, 40-50, 50+)
    e. Sex
    f. Race
    g. Co-morbid conditions (e.g., Pickwickian syndrome)
    h. Other factors (e.g., psychosocial or socioeconomic factors)

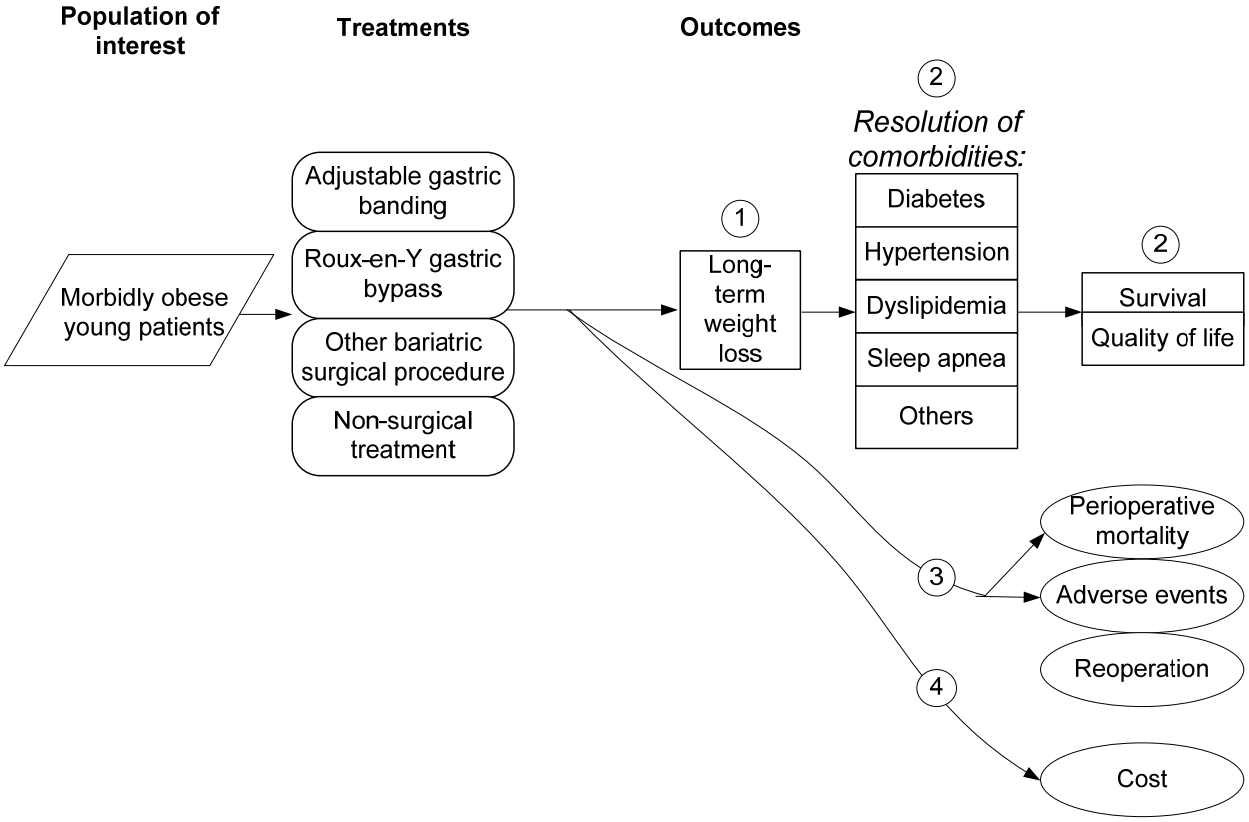
Bariatric surgery for the treatment of morbid obesity in pediatric patients is diagrammed in Figure 1 below. This figure is called an analytic framework. Such frameworks help clarify the scope of the review, the key clinical questions addressed, and the relationships between outcomes. Pediatric patients with morbid obesity enter the framework from the left and progress through treatment and outcomes to the right. The Key Questions delineate four age categories: 1) all those aged 21 or younger; 2) patients between 18 and 21; 3) patients between 13 and 17; and 4) patients 12 and younger.

For treatment, patients can either receive bariatric surgery (LAGB, RYGB, or other procedure) or non-surgical treatment for obesity (e.g., diet, exercise, pharmacological agents, behavioral modification). In the long term, the chosen intervention may lead to weight loss, which is addressed in Key Question 1. Weight loss, in turn, may cause improvement or resolution of comorbidities (e.g., diabetes, hypertension, others). Finally, the weight loss and any consequent comorbidity resolution may increase long-term survival and improve quality of life. These outcomes of potential benefit are addressed in Key Question 2. Key Question 3 involves safety, including perioperative mortality, adverse events, and the need for re-operation to correct problems with the original operation. Additional Key Questions involve costs (Key Question 4)

and whether certain patient characteristics are associated with differences in outcomes (Key Question 5).

For all Key Questions, we examined outcome data separately for different bariatric procedures. This is due to variation among procedures in the mechanism(s) for inducing weight loss. Consequently, different procedures would be expected to result in different amounts of weight loss, different rates of comorbidity resolution, different types of harms and adverse events, different costs, and different associations between patient characteristics and outcomes.

Figure 1. Analytic Framework



Literature Searches

The clinical studies included in this technology assessment were identified using a multi-staged study selection process, and were based on inclusion criteria that were determined *a priori*. Use of *a priori* inclusion criteria reduces the risk of bias because the decision to include or exclude each study is independent of the results of the study. In the first stage of the selection process, we performed a comprehensive literature search using broad criteria. In the second stage, we retrieved all articles that appeared to meet the *a priori* inclusion criteria, based on their published abstracts. In the final stage of the study selection, we reviewed the full text of each retrieved article, assessed its quality, and verified whether or not it met the *a priori* inclusion criteria.

One characteristic of a good technology assessment is a systematic and comprehensive search for information. Such searches distinguish systematic reviews from traditional literature reviews. Traditional literature reviews use a less rigorous approach to identifying and obtaining literature, making it possible for a reviewer to include primarily articles that agree with a particular perspective, and to ignore articles that do not. Our approach precludes this potential reviewer bias because we obtained and included articles according to explicitly determined *a priori* criteria.

Briefly, we searched 15 external and internal databases, including PubMed and Embase, for relevant studies. In addition, we searched more than 1,600 journals and supplements maintained in ECRI Institute's collections to determine if they contained relevant information. We also examined the bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature includes reports and studies produced by local government agencies, private organizations, educational facilities, and corporations that do not appear in the peer-reviewed literature.) A complete list of the databases searched and the search strategy used to identify relevant studies are presented in Appendix A (page 81). The last search was conducted on May 2, 2007.

Study Inclusion Criteria

Use of explicit inclusion criteria, decided upon before data have been extracted, is a vital tool in preventing reviewer biases. Some of these *a priori* criteria are based on study design, and other criteria ensure that the evidence is not derived from unusual patients or interventions and/or outmoded technologies. Finally, we also developed criteria to ensure that we focused our analysis on the outcomes that are of most interest to patients.

The inclusion criteria were:

1. Study must have reported on at least one of the outcomes that are the focus of this report. *Other outcomes are beyond the scope of this report.*
2. Study must be published in English.
   Moher et al have demonstrated that exclusion of non-English language studies from meta-analyses has little impact on the conclusions drawn.(45) Juni et al found that non-English studies typically were of lower methodological quality and that excluding them had little effect on effect size estimates in the majority of meta-analyses they examined.(46) Although we recognize that there may be situations in which exclusion of

non-English studies could lead to bias, we believe that it is insufficiently likely that we cannot justify the time and cost of translations to identify studies of acceptable quality for inclusion in our reviews.

3. Study must be published as a peer-reviewed full article. Meeting abstracts will not be included.
   Published meeting abstracts have not been peer-reviewed and often do not include sufficient details about experimental methods to permit one to verify that the study was well designed.(47,48) In addition, it is not uncommon for abstracts that are published as part of conference proceedings to describe studies that are never published as full articles.(49-52)
4. The study must have enrolled three or more individuals per treatment arm.
   The results of case studies are typically more variable and less generalizable than those of larger studies.
5. When several sequential reports from the same study center are available, only outcome data from the largest and most recent report will be included. However, we will use relevant data from earlier and smaller reports if the report presents pertinent data not presented in the larger, more recent report.
   This criterion prevents the double-counting of patients.
6. If the study was a controlled trial directly comparing a surgical approach to a non-surgical approach, the groups must have been well-matched at baseline (for age, sex, and pre-surgical BMI) in order to include the data from the non-surgical group.
   This criterion prevents against selection bias.
7. If the study enrolled patients who received different procedures, data must have been reported separately for each procedure, or at least 85% of patients must have received the same procedure.
   Because different procedures may have different patient indications and may result in different outcomes, combined data may not be easily interpreted.
8. For weight outcomes, the study must have reported data for at least half of the pertinent enrolled patients at one or more years after surgery.
   If data were reported for less than half of the enrolled patients, the reported data may be unrepresentative of the experience of typical patients. Short-term weight loss can be transient, and sustained weight loss is defined in this report as one year or more after surgery.
9. For other outcomes, the study must have reported data for at least half of the enrolled patients, and there was no minimum length of followup.
   For other outcomes (e.g., improvements in comorbidities, adverse events), all time points are of interest.
10. For quality-of-life outcomes, the study must have measured quality of life before and after surgery using a previously validated instrument.
    This criterion means that quality of life data would not depend on patients' memory of their quality-of-life before surgery.
11. All patients must have been age 21 or less.
    This report only considers pediatric patiens.

12. Study must report data on one of the following surgical procedures:
    - Adjustable gastric banding (AGB)
    - Roux-en-Y gastric bypass (RYGB)
    - Vertical banded gastroplasty (VBG)
    - Silastic ring vertical gastroplasty (SRVG)
    - Mini gastric bypass (MGB)
    - Combined VBG-RYGB (also called the Fobi pouch procedure)
    - Biliopancreatic diversion (BPD)
    - Biliopancreatic diversion with duodenal switch (BPD/DS)

    The above-listed procedures are currently being performed. Some bariatric procedures, such as horizontal gastroplasty and jejunoileal bypass (JIB), are not currently performed and were therefore outside the scope of this report.

Evaluation of the Stability and Strength of the Body of Evidence

To evaluate the stability and strength of a body of literature, we used a formal rating system.(53) This system employs decision points that collectively yield an overall category that describes the strength of the evidence for a *quantitative* estimate and *qualitative* conclusion as strong, moderate, weak, or unacceptably weak. The qualitative conclusion addresses the question, "Does it work?" The quantitative estimate addresses the question, "How well does it work?" This distinction allows flexibility in ratings of different aspects of the evidence. For example, an evidence base can be considered weak in terms of the precise *quantitative* estimate of effect (e.g., if estimates vary widely among studies), but strong or moderate with respect to the qualitative conclusion (e.g., if all studies nevertheless demonstrate the same direction of effect).

The system addresses five general aspects of the evidence: quality, quantity, consistency, robustness, and magnitude of effect. Quality refers to the degree of potential bias in the design or conduct of studies. Quantity refers to the number of studies and the number of enrolled patients. Consistency addresses the degree of agreement among the results of available studies. Robustness involves the constancy of conclusions in the face of minor hypothetical alterations in the data. Magnitude of effect concerns the quantitative amount of benefit that patients experience after treatment, and it is only considered in the qualitative section of the system. These concepts, and the rules we used to incorporate the concepts in this report, are described more fully in Appendix C (starting on page 86).

Statistical Methods

When three or more studies of the same surgical procedure reported data on the same outcome, we performed DerSimonian and Laird random-effects meta-analysis.(54) Meta-analysis allows the pooling of data from different studies to maximize the informativeness of the evidence. Also, it provides a means for formally identifying and exploring important differences among the results of different studies (heterogeneity). We analyzed weight data using body mass index (BMI). For dichotomous outcomes, we used the odds ratio as the effect size metric.

Because all patients in all studies had undergone multiple unsuccessful attempts at weight loss prior to surgery, our analyses assumed that they would not have lost weight without surgery. Further, the analyses assumed that medical comorbidities associated with obesity would not have resolved without surgery. These assumptions were tested in robustness analyses; specifically, we investigated alternative assumptions that without surgery patients might have lost a small amount of weight (up to 1.3 BMI units) or might have experienced a small rate of comorbidity resolution (5%).

For weight loss, a clinically significant amount was defined as 7% of body weight, because patients who lose this amount of weight have been shown by other researchers to yield substantial reductions in medical comorbidities of obesity.(55,56) This criterion is more stringent than the definition of clinically significant weight loss of 5% body weight that is used by the U.S. FDA.(57)

For meta-analysis of before-after studies of change in BMI, the computation of an effect size requires a patient-level correlation between pre-surgical BMIs and post-surgical BMIs. Some studies reported such individual patient data, so we calculated the correlation for each of these studies, and then performed a random-effects meta-analysis of these correlations. We then used the summary correlation (0.60) as an imputed correlation in studies that had not provided individual patient data. In subsequent robustness tests, we used the 95% confidence bounds of this correlation to determine sensitivity to the choice of correlation.

Other statistical robustness tests included the removal of one study at a time to determine whether the conclusion was driven by any single study; cumulative meta-analysis to determine sensitivity to publication date; a sufficiently narrow confidence interval around a summary effect size to determine the robustness of a quantitative estimate; imputation of a small amount of BMI loss (0.5 to 1.3 units) without surgery to determine sensitivity of conclusions to the assumption of no weight loss without surgery; and imputation of a small rate of comorbidity resolution (5%) without surgery to determine sensitivity of conclusions to the assumption of no comorbidity resolution without surgery.

For Key Question 5, we calculated correlations between patient characteristics and outcomes in studies that reported patient-level data. If there were three studies of the same association, we performed a meta-analysis of the correlations using DerSimonian and Laird random-effects meta-analysis.(54)

Specific Methods for Key Question 4

Our preliminary review of potentially relevant clinical studies for analysis indicated that these clinical studies did not provide any cost data regarding pediatric bariatric surgeries. An extensive search and review of other literature on the topic suggested that the available evidences from the literature were not sufficient for building a detailed cost profile covering various bariatric procedures in the age groups of interest. Therefore, we decided to use a mixed approach to Question 4. While we planned to incorporate some of the cost information collected from the literature, we primarily depended on the Healthcare Cost and Utilization Project (HCUP) data sets to build the cost profile.

In building the profile, we only pursued direct costs associated with bariatric surgery and three-year related postoperative care. Indirect cost (e.g., those associated with failed procedures and loss of school hours) was not investigated. Our goal was to build a cost profile that covers hospital inpatient services, typical postoperative care for the first three years after surgery, and relevant professional services. Where cost data were not identifiable, we used charge data instead to provide policymakers a more complete and informative picture.

Identifying Hospital Inpatient Cost

To identify hospital inpatient cost, we used the Healthcare Cost and Utilization Project (HCUP) data.

HCUP Data

The HCUP databases are developed through a Federal-State-Industry partnership and sponsored by the Agency for Healthcare Research and Quality (AHRQ). HCUP includes the largest collection of longitudinal hospital care data in the United States, with all-payer, encounter-level information beginning in 1988, which enables research on a broad range of health policy issues including cost and quality of health services. HCUP consists of several databases including Nationwide Inpatient Sample (NIS), the State Inpatient Database (SID), the Kids' Inpatient Database (KID), the State Ambulatory Surgery Databases (SASD), and the State Emergency Department Databases (SEDD).

For our inpatient cost analyses, we utilized NIS for 2004. NIS is the largest all-payer inpatient care database in the United States. It contains data from approximately 8 million hospital stays each year and is the only national hospital database with charge information on all patients, regardless of payer. The NIS 2004 data set was the most recent NIS available to the public. It contains discharge data from 1,004 hospitals located in 37 states, approximating a 20-percent stratified sample of U.S. community hospitals in 2004. We decided to use NIS instead of the KID for two reasons. First, NIS is updated more frequently than KID (the most recent KID dataset is for 2003). Second, KID only contains data for patients of up to 20 years of age, while this evidence report covers a population of up to 21 years of age. Our analysis of the 2004 NIS data showed that nearly a quarter (103) of the 415 pediatric bariatric surgery cases identified from the dataset were those for patients who were 21 years old.

In addition to NIS 2004, we also used SID 2002-2004 databases for the State of Washington (SID WA) to generate state-specific inpatient cost information. The SID WA data sets contained the universe of the inpatient discharge abstracts in the State of Washington. They contain a core

set of clinical and nonclinical information on all patients covered by Medicare, Medicaid, private insurance, and the uninsured. SID WA 2004 is the most recent SID available to the public.

Case Selection

The HCUP data sets use the International Classification of Diseases, Ninth Revision (ICD-9), coding system to classify procedures and diagnoses. However, the ICD-9 system does not have specific codes for all bariatric procedures currently performed. We consulted previous studies(34,58-60) and the Centers for Medicare & Medicaid Services' billing guidelines to develop a list of ICD-9 codes to identify bariatric surgery cases in the HCUP databases. The following are the criteria that we used for case selection:

- Cases must have a diagnosis code for obesity (278.0, 278.00, 278.01, 278.1, and 278.8) and a procedure code for gastric bypass (44.31 and 44.39), gastroplasty (44.69), laparoscopic gastric bypass (44.38), laparoscopic gastroplasty (44.68), and laparoscopic gastric restrictive procedures (44.95).

- Cases that were unlikely to be elective bariatric surgeries were excluded based on diagnosis codes for gastrointestinal tract neoplasm (150.0-159.9), in-situ cancers (230.1-130.9), inflammatory bowel disease (555.0-556.9), or noninfectious colitis (557.0-558.9), and emergent admission codes (admission-type variable = emergent or urgent and/or admission-source variable = emergency department or other hospital).

Because different bariatric procedures might have been coded under the same ICD-9 procedure codes in 2004, differentiation between various procedures (such as LAGB, RYGB and VBG) with certainty is impossible. In order to perform cost analyses at the procedure level, we created two categories—bypass procedures and restrictive procedures—based on the similarity in resource consumption and involved surgical techniques. The bypass category would mostly consist of RYGB, long-limb gastric bypass and biliopancreatic diversion (with or without duodenal switch) cases. The restrictive category would mostly consist of LAGB and VGB cases. We used ICD-9 procedure codes 44.31, 44.39, and 44.38 to capture the cases in the bypass category and used codes 44.69, 44.68, and 44.95 to capture the cases in the restrictive category. If a case had codes for both categories, we assumed that the patient had undergone a bypass procedure.

We further broke each of the two procedure categories into two sub-categories by open approach or laparoscopic approach. The codes for laparoscopic bariatric procedures (44.38, 44.68 and 44.95) were added to the ICD-9 system on October 1, 2004. In addition to using these three codes, we used concurrent procedure coding to capture the laparoscopic cases performed before October 1, 2004. We considered concurrent procedure coding with any laparoscopic code—including 54.21, 47.01, 47.11, 51.23, 54.51, 65.01, 65.25, 65.31, 65.39, 65.41, 65.63, 65.64, 65.81, or 68.51—as evidence that the procedure was performed laparoscopically. Appendix D (page 96) contains the information on the codes discussed in this section.

Data Analyses

We used SPSS 15.0 for data processing. We analyzed both charge and cost data. Because HCUP data sets do not provide cost values directly, we first converted charge values to cost values using HCUP hospital-specific cost-to-charge ratios (CCRs). The CCRs were based on hospital

accounting reports from the Centers for Medicare and Medicaid Services (CMS) and had factored in both operating costs and capital-related costs. Because 32% of hospital-specific CCR values were missing, we used group average CCRs to substitute the missed hospital-specific values. The HCUP hospital groups are defined by state, urban/rural, investor-owned/other, and number of beds. The group average CCR is a weighted average for the hospitals in the group, using the proportion of group beds as the weight for each hospital. Independent-samples t-test was used to examine if significant differences existed in inpatient cost and charge between age groups.

Identifying Cost of Professional Services

The HCUP inpatient hospital charge does not include the fee charged by the surgeon for performing bariatric surgery. Therefore, we looked to the Medicare Physician Fee Schedule (MPFS) from CMS to obtain data regarding professional service cost. The MPFS amounts are set by CMS based on resources consumed for the services provided by physicians and other health professionals. The MPFS amounts can be considered as proxy measures of professional service costs.

Identifying Relevant Postoperative Care Cost

To develop a list of typical care services after pediatric bariatric surgery, we first consulted the clinical studies included for our review as well as several others references.(61-63) We considered the following clinical activities as part of a typical postoperative treatment plan for pediatric bariatric surgery:

- Regular follow-up visits (e.g., 1-2 weeks after surgery and then monthly for the first postoperative year and then every 3 months after the first year) to the surgeon and other specialists (e.g., psychologist and dietitian) to identify potential complications and to reinforce compliance with post-operation treatment plans.
- Periodic (commonly at 3, 6, 9, and 12 months postoperatively, and then yearly) laboratory tests (including complete blood counts, blood chemistry profile, lipid panel, metabolic panel, nutrition panel, thyroid function tests, glucose tolerance test with insulin and hemoglobin A_{1c}, liver function tests) to monitor nutrition status and to detect early hematologic or metabolic complications.
- Annual esophagrams to evaluate for subclinical gastric pouch or esophageal dilatation (and to reconfirm band position for LAGB).
- Radiographic and endoscopic studies when symptoms of persistent dysphagia, gastroesophageal reflux, or suspected devices failure were noted.
- Band diameter adjustments for LAGB.
- Post-operative lifetime vitamin and mineral supplements.
- Treatments for various complications (e.g., adjustment, removal or replacement of band, revision of restrictive or bypass procedures, incision hernia repair, medical treatment of GERD or marginal ulcer, and re-operation for bleeding)

Based on the same rationales discussed in the previous section, we resorted to MPFS to obtain data on professional charges for postoperative care. We used the Medicare's Clinical Laboratory Fee Schedule to obtain data on the fee amounts for postoperative outpatient laboratory services.

Building Cost Profiles for Two Scenarios

Given that cost may vary greatly across different bariatric procedures and may fluctuate significantly under different circumstances (e.g., whether or not the patient had experienced any serious postoperative complications), we used two scenarios to synthesize the costs that we had identified from the previous steps. In both scenarios, we assumed that the patient had a smooth recovery without a major complication leading to costly medical or surgical interventions. We limited our postoperative cost calculation only to the first three years because we believe that the annual postoperative care cost thereafter would become stabilized and be similar to the cost for the third postoperative year. Before they were synthesized, all cost data were converted to 2007 dollars using the Consumer Price Index developed by the U.S. Bureau of Labor Statistics.

Scenario One: LABG without Major Complications

In this scenario, the patient underwent LAGB. The hospital inpatient cost for LAGB includes a cost of approximately $3,200 for the LAP-BAND® unit (BioEnterics, Corporation, Carpinteria, CA).[2] We made following assumptions to reflect standard of care in post-LAGB treatment(61-63):

- The patient had follow-up office visits at 1-2 weeks after surgery for wound check and then monthly for the first postoperative year, every 3 months for the second postoperative year, and every six months after the second postoperative year to detect potential complications and to reinforce compliance with post-operation treatment plans. (We noticed that the postoperative follow-up frequencies in the Nadler study(61) were higher than what other references(62,63) suggested. To be conservative, we used the Nadler standard. We believe that more frequent followups are appropriate for the pediatric population given the concerns about low compliance rates among pediatric patients.)
- The patient had office visits twice for diet counseling and once for psychological evaluation in the first postoperative year.
- The patient had the following tests at 3, 6, 9, and 12 months postoperatively and then yearly to detect nutritional and metabolic complications: complete blood counts, blood chemistry profile, lipid panel, metabolic panel, nutrition panel, thyroid function tests, glucose tolerance test with insulin and hemoglobin A_{1c}, liver function tests.
- The patient received annual esophagrams to evaluate for gastric pouch or esophageal dilatation and to reconfirm band position.

[2] LAP-BAND® pricing information was obtained from the ECRI Institute's medical device price comparison system.

- The patient received gastric band diameter adjustments four times in the first year and twice in the second year.
- The patient did not experience any complication leading to costly medical or surgical treatments.

We assumed that most of the laparoscopic restrictive cases we identified from the HCUP NIS 2004 data set were LAGB cases, given the increasing popularity of the procedure in recent years. Therefore, we use the median inpatient cost (in 2007 dollars) for the subcategory to substitute for the hospital inpatient cost for an average LAGB case.

Scenario Two: Open RYGB without Major Complications

In this scenario, the patient received RYGB through the open approach. We made following assumptions to reflect standard of care in post-RYGB treatment(61-63):

- The patient had follow-up office visits at 1-2 weeks after surgery for wound check and then monthly for the first postoperative year, every 3 months for the second postoperative year, and every six months after the second postoperative year to detect potential complications and to reinforce compliance with post-operation treatment plans. (For the reason mentioned above, we assumed more frequent followup for the pediatric population than what some of the references suggested.(62,63))
- The patient had office visits twice for diet counseling and once for psychological evaluation in the first postoperative year.
- The patient had the following tests at 3, 6, 9, and 12 months postoperatively and then yearly to detect nutritional and metabolic complications: complete blood counts, blood chemistry profile, lipid panel, metabolic panel, nutrition panel, thyroid function tests, glucose tolerance test with insulin and hemoglobin A_{1c}, liver function tests.
- The patient received annual esophagrams to evaluate for subclinical gastric pouch or esophageal dilatation.
- The patient did not experience any complication leading to costly medical or surgical treatments.

We used the median inpatient cost (in 2007 dollars) of open bypass procedure subcategory that we identified using the HCUP NIS 2004 data set to substitute the hospital inpatient cost for an average RYGB case.

Specific Methods for Nonsurgical Approaches in Key Questions 3 and 4

Given the vast amount of published literature available on nonsurgical interventions, our time and resource limitations, and the emphasis of this report on surgical approaches, we restricted our evaluation of the safety profile of nonsurgical approaches to systematic reviews. To be included, a systematic review had to meet the following criteria:

- The review is published in English.
- The review was published in 2000 or later.
- The review is on treatments for obesity/morbid obesity with a dedicated section on potential harms of nonsurgical approaches for the pediatric population.
- A comprehensive literature search was performed using at least two electronic sources (e.g., Central, EMBASE, and MEDLINE).
- Inclusion and exclusion criteria for study selection were provided.

The quality of included systematic reviews would be evaluated using a measurement tool for assessment of multiple systematic reviews (AMSTAR).(64) We decided to summarize the findings from these reviews qualitatively.

For the cost profile of nonsurgical approaches, we included all published materials that have a cost component for nonsurgical approaches to obesity management in the pediatric population. To be included, published material must meet the following criteria:

- It was published in 2000 or later.
- The cost data were reported for treatments conducted in U.S settings. Foreign studies were excluded.
- The cost data reported reflect the national or a regional pattern or trend. Publications containing cost data only for an individual institution or provider are excluded.
- Adequate information is provided to permit an evaluation of data credibility.

We decided to summarize the cost data reported in published materials qualitatively.

Results

Evidence Base

Included Studies

The results of literature searches, abstract reviewing, full-article retrieval, and study exclusion are depicted in Figure 2 below. Of the 150 abstracts identified by searches, we retrieved 35 articles, and we excluded 12 of these because they did not meet the inclusion criteria. The list of excluded studies appears in Appendix B (page 85).

After these exclusions, 16 unique studies in 23 publications comprised the evidence base (Table 2). Seven studies reported outcomes after laparoscopic adjustable gastric banding (LAGB), six after Roux-en-Y gastric bypass (RYGB), two after vertical banded gastroplasty (VBG), and one after combined VBG-RYGB. One study (Barnett)(65) reported data separately for RYGB and VBG. Additional study characteristics and patient characteristics are listed in Table 19 and Table 20 of Appendix E, respectively.

Patients' ages and pre-surgical BMIs are displayed graphically in Figure 3 and Figure 4. The average age ranged from 15.6 years to 18.1 years, with little difference in mean age among bariatric procedures. None of the studies focused exclusively on patients aged 18-21, or on patients aged 12 or less. Four studies enrolled only patients aged 13-17: the Nadler study of LAGB, the Barnett study of RYGB and VBG, the Strauss study of RYGB, and the Capella study of combined VBG-RYGB.

For pre-surgical BMI (Figure 4), the weighted average was lower for LAGB (BMI = 45.1 kg/m^2) than for RYGB (BMI = 51.8 kg/m^2). This observation conforms to the conventional use of purely restrictive procedures (such as LAGB) for less obese patients, or the use of more malabsorptive procedures (such as RYGB) for those who are more obese. For reference, a 17-year old boy of average height with a BMI of 48 kg/m^{2}weighs approximately 152 kilograms (334 pounds), and the corresponding 17-year-old girl weighs approximately 131 kilograms (289 pounds).

This report defines "clinically significant" weight loss as 7% of body weight (see *Methods* section). In the included LAGB studies, 7% of body weight in the enrolled patients corresponds to 3.5 BMI units. In the included RYGB studies, 7% of body weight in the enrolled patients corresponds to 4 BMI units. In the included studies of VBG or combined VBG-RYGB, 7% of body weight in the enrolled patients corresponds to 3.9 BMI units.[3]

Prior to surgery, all patients had undergone multiple unsuccessful attempts at weight loss using non-surgical methods (see studies' descriptions of prior attempts in Table 19 of Appendix E). We believe that it is reasonable to assume that these patients would not have lost any weight if they had not had surgery. One of the 16 studies reported a control group of patients who were not treated with bariatric surgery (the Lawson study of RYGB).(66) This control group included 12 patients who had completed one year in a non-surgical pediatric weight management

[3] These BMI units are based on baseline BMIs and calculations of the average heights of patients, which was possible in studies that reported both BMI and weight data.

program. However, patients were not randomly assigned to groups, the control group patients weighed statistically significant less at baseline than surgical patients, and the study did not report any medical comorbidities among control group patients (whereas surgical patients had several comorbidities). These factors mean that the groups were not well-matched at baseline, thus we excluded the data from this control group, and included only the data from the surgical group.

Regarding the surgical procedures, five of the seven LAGB studies used the LAP-BAND® (Inamed Health, Santa Barbara, CA) one used the Swedish Adjustable Gastric Band (SAGB; Ethicon Endo-Surgery, Cincinnati, OH), and one used the SAGB in 74% of patients and the LAP-BAND® in the remaining 26%. Of the six RYGB studies, two used a laparoscopic approach, three used an open approach, and one used an open approach for 94% of procedures and a laparoscopic approach for the remaining 6%. The three VBG studies were all performed using an open approach. Additional procedure details, along with the center locations and surgical date ranges, appear in Table 19 of Appendix E.

Figure 2. Study Attrition Diagram

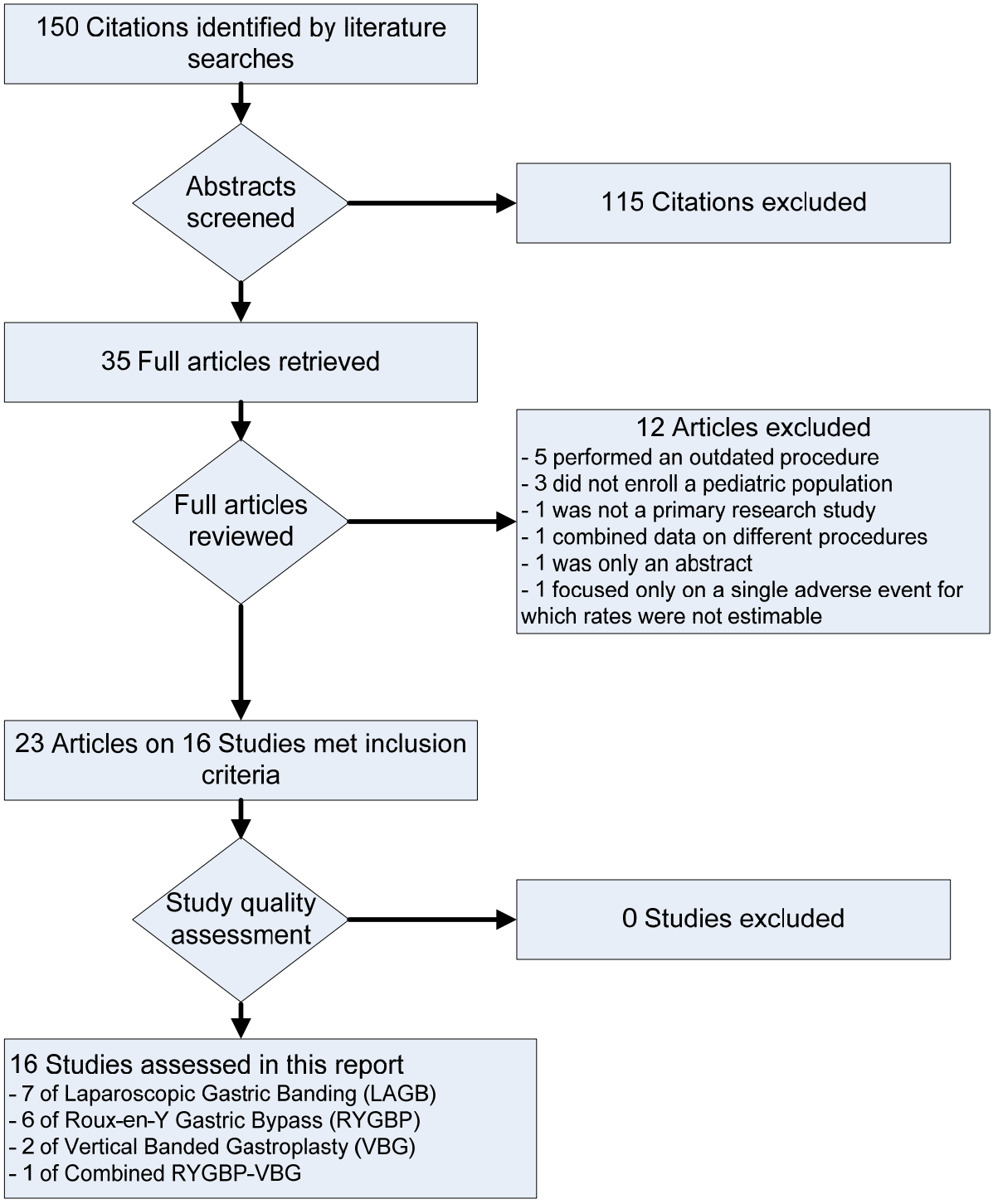


Table 2. Included Studies

Study	Dates of surgery	Number of patients	Mean age before surgery (range)	Mean BMI in kg/m^2 before surgery (range)
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)				
Nadler (2007)(61)	9/2001 – 2/2006	53	15.9 (13 - 17)	47.6 (Range NR)
Yitzhak (2006)(67)	2000 – 2006	60	16 (9 - 18)	43 (35 - 61)
Silberhumer (2006)(68,69)	1998 - 2004	50	17.1 (9 - 19)	45.2 (32.5 - 76.6)
Angrisani (2005)(70)	1/1996 – 12/2003	58	18.0 (15 - 19)	46.1 (34.9 - 69.25)
Fielding (2005)(71-73)	1998 – 2003	41	15.6 (12 - 19)	42.4 (31 - 71)
Horgan (2005)(74)	2001 - 2003	4	17.8[a] (17-19)	50.5[a] (40 - 61)
Abu-Abeid (2003)(75)	Not reported	11	15.7 (11 - 17)	46.6 (38 to 56.6)
Studies of Roux-en-Y Gastric Bypass (RYGB)				
Collins (2007)(76,77)	1999 - 6/2005	11	16.5 (15-18)	50.5 (42 - 66)
Lawson (2006)(66,78-80)	5/2001 – 10/2003	35	17.6 (13 - 21)	56.5 (41.9 - 95.5)
Barnett (2005)[b](65)	1978 – 2001	14	15.7 (13 - 17)	51 (Range NR)
Sugerman (2003)(35)	1981 – 1/2002	33	16.0 (12.4 - 17.9)	52 (38 - 91)
Strauss (2001)(36)	4/1985 – 5/1999	10	16.2[a] (15 - 17)	53.6[a] (41.4 - 70.5)
Rand (1994)(37)	1/1979 – 12/1990	34	17 (11 - 19)	47 (38 - 66)
Studies of Vertical Banded Gastroplasty (VBG)				
Barnett (2005)[b(65)]	1978 – 2001	14	15.7 (13 - 17)	60 (Range NR)
Greenstein (1995)(81)	3/1982 – 6/1994	14	17 (13 - 21)	47.8[a] (41 - 60)
Mason (1995)(82)	1980 – 1994	47	18.1 (14 - 20)	48.4 (Range NR)
Studies of Combined VBG-RYGB				
Capella (2003)(83)	5/1990 – 1/2001	19	15.6[a] (13 - 17)	49 (38 - 67)

[a] Calculated by ECRI based on reported information
[b] The study by Barnett reported data on both RYGB and VBG, thus it is listed twice.

Figure 3. Patient Age Before Surgery

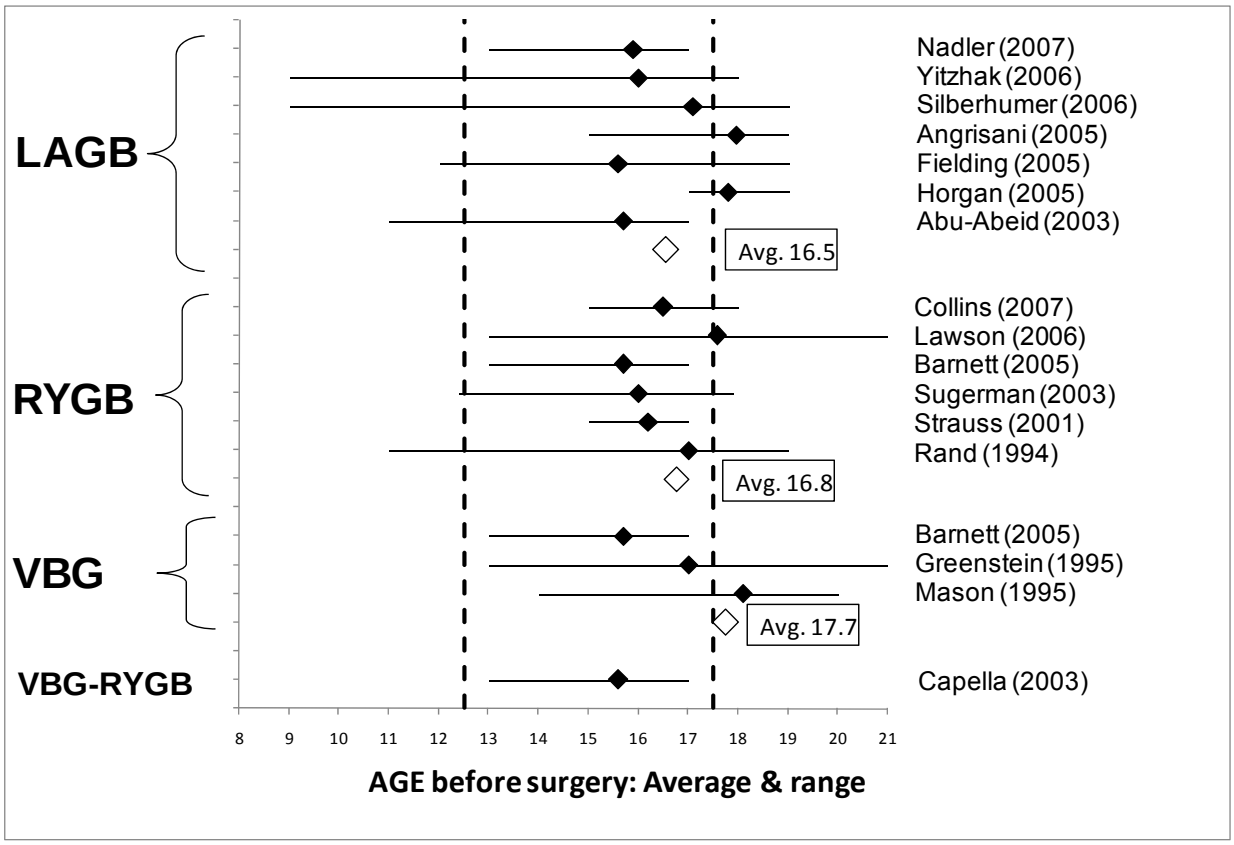
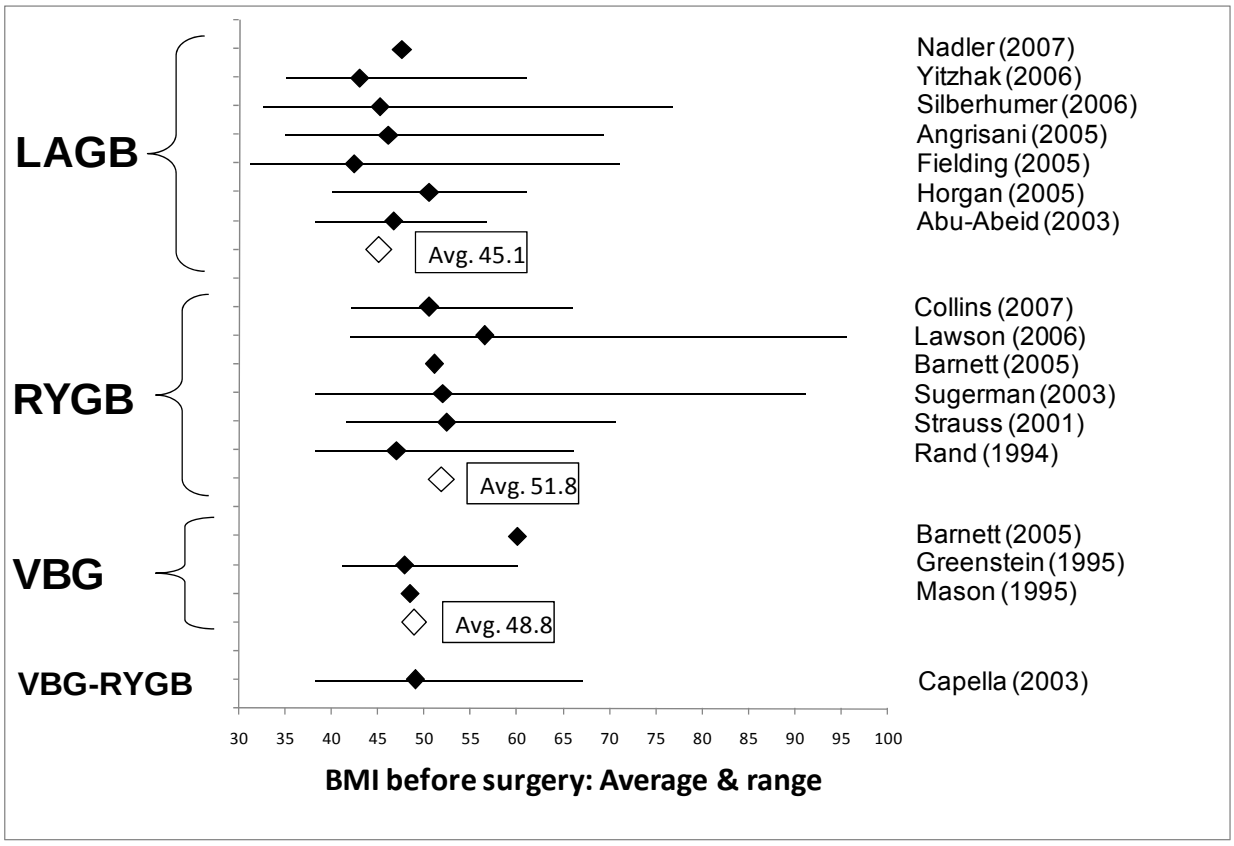


Figure 4. Patient BMI Before Surgery



Internal Validity

All studies were of moderate to low quality. Our detailed assessments appear in Table 21 of Appendix E (page 104). This section provides some insight into the quality limitations of the 16 studies. For example, 13 studies were conducted retrospectively. Retrospective design may introduce bias because when authors decided to publish the data, they were armed with the knowledge of the favorable (or unfavorable) outcomes experienced by patients. Other potential authors may have decided not to publish their analyses. If so, the *reported* outcomes would overestimate (or underestimate) the benefits of surgery. Retrospective analyses may also fail to detect certain adverse events that would have been caught with prospective data collection.

One strategy to counteract the problem of retrospectivity is to enroll all eligible patients consecutively, which was performed in 12 studies, not performed in 3 studies, and unclear in the remaining study. Consecutive enrollment helps ensure that authors did not specially select patients who experienced desired outcomes. A related quality factor is attrition: studies would ideally report long-term outcome data on *all* patients enrolled. However, with any long-term followup, there will be patients whose outcomes are not known or patients who have not reached longer timepoints. Usually it is unclear whether dropouts experienced similar outcomes as those remaining in the study, or whether recently-treated patients will eventually experience similar outcomes.

A final quality concern is financial interest. Only one of the 16 studies reported the funding source.[4] However, careful readers should realize that the 16 studies were generally conducted by bariatric surgeons, who could financially benefit from research demonstrations of good outcomes and minimal adverse events.

Generalizability

Generalizability involves the extent to which the patients and treatments in published studies are representative of typical practice. In this section, we discuss four aspects of generalizability:

- Characteristics of the patients enrolled
- Prior experience of the bariatric surgeons
- Surgical techniques used
- The setting of care

The population of interest is pediatric patients in the U.S. who are morbidly obese and willing to undergo bariatric surgery. Our inclusion ensured that all patients in all studies were among this population. Also, the included studies generally used the NIH criteria for adult bariatric surgery for patient selection (Table 19 in Appendix E). Further, no evidence from the included studies indicated any significant difference between the studied population and the population of interest in demographic, socioeconomic, or cultural aspects. These observations support the generalizability of the patients enrolled.

Studies had shown that more experienced surgeons may produce better surgical outcomes than less experienced surgeons.(84,85) The duration of the learning curve may be different for different procedures. For LAGB, Shapiro et al. (2003)(84) found that the rate of complications dropped from 37% in the first 30 cases to 7% in the next 30 cases. For laparoscopic RYGB,

[4] The Lawson study of RYGB reported that the study was partially funded by Ethicon-EndoSurgery, the manufacturer of a gastric stapling device and the Swedish Adjustable Gastric Band

a study by Schauer et al. (2003)(85) found a decrease in complications from 42% in the first 50 cases, to 30% in the next 50 cases, and to 22% in the next 50 cases.

In the included studies, the average number of pediatric cases performed by the surgeons was generally low. As shown in Table 3, only one surgeon(67) had performed more than 50 pediatric cases. However, most of the surgeons in the studies were affiliated with a surgical department that also have adult patients. Thus, the surgeons had experience from adult surgery cases, but studies did not report the prior number of surgeries performed. Because surgeons are generally cautious about performing bariatric surgeries on the pediatric population due to lack of data about the possible long-term harms to the growing body and mind, we assume that they would want to gain sufficient experience from adult cases before they ever move on to pediatric patients. According to our analysis of the Healthcare Cost and Utilization Project (HCUP) 2004 data, pediatric cases accounted for 1.68% of all bariatric surgeries performed in the U.S. Thus, assuming a random distribution of pediatric cases among adult cases, surgeons operate on approximately 60 adults before their first pediatric patient. The lack of reporting of surgeons' prior experience, however, precludes assessments of this aspect of generalizability.

With respect to the surgical techniques used, 13 of 16 studies performed either LAGB or RYGBP. These are the two most commonly performed bariatric procedures in the U.S. Three other studies described less commonly performed procedures (VBG and combined VBG-RYGBP). Regarding the use of laparoscopic techniques, all bands were placed laparoscopically, which conforms to standard practice. RYGBP was performed laparoscopically for all patients in two studies, and using an open approach for most or all patients in the other four studies. These observations generally support the generalizability of the included studies.

Studies have suggested that multidisciplinary support is crucial for satisfactory long-term outcomes of bariatric surgeries.(79) Fifteen of the 20 medical centers involved in the included studies were university-based academic medical centers (The Italian study(70) was not counted because it reported multi-center results). Academic medical centers offer good accessibility to expertise in various disciplines needed for a comprehensive pediatric bariatric surgery program. Four studies explicitly stated that the involved medical centers had a multidisciplinary pediatric bariatric program.(61,75,76,79) In general, we feel that the findings of our study are generalizable to those procedures performed in academic centers or other settings that had a multidisciplinary pediatric bariatric surgery program. Likely, the care setting at these institutions was more advanced than in other settings in which pediatric bariatric surgery might occur.

In addition, five of the seven LAGB studies were conducted at non-U.S. institutions (two in Israel, and one each in Italy, Austria, and Australia). Only fifty-seven (21%) of the 277 LAGB cases were from the two U.S. studies. Nonetheless, there was no evidence from these studies suggesting any demographic, clinical, or socioeconomic, differences between U.S. and non-U.S. populations. Further, there was no evidence either suggesting that LAGB procedures were performed differently in different regions. All of the studies on RYGB, VGB, and combined VGB-RYGB were conducted at U.S. institutions.

Table 3. Characteristics of Centers and Surgeons Included Studies

Study	Country	Center and bariatric program	Type of surgical department	Number of surgeons involved	Total patient number	Case number per surgeon
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)						
Nadler (2007)(61)	USA	One academic medical center with a comprehensive bariatric program	Division of Pediatric Surgery	3	53	18
Yitzhak (2006)(67)	Israel	One academic medical center	Department of Surgery	1	60	60
Silberhumer (2006)(68,69)	Austria	Three centers, including one academic medical center	Departments of Surgery	<1	50	≤25
Angrisani (2005)(70)	Italy	Multicenter	Not reported	<1	58	≤29
Fielding (2005)(71-73)	Australia	One private center with a comprehensive bariatric program	Department of Surgery	1	41	41
Horgan (2005)(74)	USA	One academic medical center	Division of General Surgery and Minimally Invasive Surgery, and Division of Pediatric Surgery	Not reported	4	≤4
Abu-Abeid (2003)(75)	Israel	One academic medical center with a multidisciplinary bariatric program	Department of Surgery B and Endoscopic Surgery	Not reported	11	≤11
Studies of Roux-en-Y Gastric Bypass (RYGB)						
Collins (2007)(76,77)	USA	One academic medical center with a multidisciplinary bariatric surgery program	Division of Minimally Invasive Surgery	Not reported	11	≤11
Lawson (2006)(66,78,79)	USA	Three pediatric academic centers with a comprehensive weight management program	Division of Pediatric Surgery, Department of Surgery, Division of Pediatric Surgery	Multiple	39	13
Barnett (2005)(65)	USA	One academic medical center	Department of Surgery	1	15	15
Sugerman (2003)(35)	USA	One academic medical center	Department of Surgery	Not reported	33	≤33
Strauss (2001)(36)	USA	One academic medical center	Department of Surgery	1	10	≤10
Rand (1994)(37)	USA	One regional medical center	Department of Surgery	1	34	34

Study	Country	Center and bariatric program	Type of surgical department	Number of surgeons involved	Total patient number	Case number per surgeon
Studies of Vertical Banded Gastroplasty (VBG)						
Greenstein (1995)(81)	USA	Two centers including one academic medical center	Department of Surgery	1	18	18
Mason (1995)(82)	USA	One academic medical center	Department of Surgery	Not reported	47	≤47
Studies of Combined VBG-RYGBP						
Capella (2003)(83)	USA	One academic medical center	Department of Surgery	Not reported	19	≤19

Key Questions Addressed by Included Studies

The studies included for each Key Question are listed in Table 4 below. For reduction in BMI (Key Question 1), we included the data from five of seven LAGB studies, five of six RYGB studies, one of three VBG studies, and one study of the combined VBG-RYGB procedure. For comorbidities and quality of life (Key Question 2), we included data from three LAGB studies and four RYGB studies. For adverse events (Key Question 3), data from all 16 studies were included. None of the studies were included for cost data (Key Question 4), thus we used alternative data sources for that question (see ***Results*** section below). For the association between patient characteristics and outcomes (Key Question 5), we included data from two LAGB studies, one RYGB study, one VBG study, and the combined VBG-RYGB study.

Table 4. Key Questions Addressed

Study	Key Question				
	1[b]	2[c]	3	4	5[d]
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)					
Nadler (2007)(61)			✓		
Yitzhak (2006)(67)	✓	✓	✓		
Silberhumer (2006)(68,69)	✓	✓	✓		
Angrisani (2005)(70)	✓		✓		
Fielding (2005)(71-73)	✓		✓		✓
Horgan (2005)(74)			✓		
Abu-Abeid (2003)(75)	✓	✓	✓		✓
Studies of Roux-en-Y Gastric Bypass (RYGB)					
Collins (2007)(76,77)	✓	✓	✓		
Lawson (2006)(66,78-80)	✓	✓	✓		
Barnett (2005)[a](65)			✓		
Sugerman (2003)(35)	✓	✓	✓		
Strauss (2001)(36)	✓	✓	✓		✓
Rand (1994)(37)	✓		✓		
Studies of Vertical Banded Gastroplasty (VBG)					
Barnett (2005)[a](65)			✓		
Greenstein (1995)(81)	✓		✓		✓
Mason (1995)(82)			✓		
Studies of Combined VBG-RYGB					
Capella (2003)(83)	✓		✓		✓

[a] Barnett reported data on both RYGB and VBG, thus it is listed twice.

[b] Four studies reported BMI data that did not meet inclusion criteria for the following reasons: The study by Nadler did not report 1+ year data for at least 50% of patients. The study by Hogan did not report 1+ year data for at least three patients. The study by Barnett did not report the length of followup of patients receiving specific procedures. The study by Mason was rated very low quality for BMI data and therefore was excluded from Key Question 1.

[c] Four studies reported quality-of-life data that did not meet inclusion criteria for the following reasons. In three studies (Yitzhak, Rand, Greenstein), the quality of life instrument was not previously validated, and only postoperative data were reported. In the fourth study (Collins), the quality of life instrument was not administered both before and after surgery. Barnett reported comorbidity resolution data, but these data were combined for three bariatric procedures, and therefore were excluded. Three other studies (Fielding, Horgan, Greenstein) reported data for comorbidity resolution, but there were no more than three patients for any single comorbidity, so the data were excluded.

[d] Key Question 5 was addressed by studies reporting individual patient data or studies that reported the necessary correlation between a patient characteristics and an outcome. A secondary publication(69) of the Silberhumer study reported individual patient data, but 1+ year individual weight data were only reported for only three of eight patients. A secondary publication(77) of the Collins study reported individual patient data, but 1+ year individual weight data were only reported for only three of 11 patients. Horgan reported individual patient data, but only reported 1+ year individual weight data for only two of four patients.

Key Question 1: Does pediatric bariatric surgery lead to sustained and clinically significant weight loss compared to non-operative approaches?

a. In patients aged 21 or less
b. Specifically in patients aged 18-21
c. Specifically in patients aged 13-17
d. Specifically in patients aged 12 or less

ECRI Institute evidence assessments:

- **Laparoscopic Adjustable Gastric Banding (LAGB) for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches. Strength of evidence: Moderate.**
- **Roux-en-Y Gastric Bypass (RYGB) for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches. Strength of evidence: Moderate to Weak.**
- **The evidence is insufficient to permit quantitative estimates of the precise amount of weight loss after any bariatric surgical procedure for pediatric patients.**
- **The evidence is insufficient to permit any conclusions about weight loss after other bariatric surgical procedures for pediatric patients.**
- **The evidence is insufficient to permit any conclusions about weight loss in specific age groups (18-21, 13-17, 12 or less)**

Patients Aged 21 or Less

The sections below describe the details of our analyses, separately for each bariatric surgical procedure. All evidence tables appear in Appendix E starting on page 96, including study and treatment details (Table 19), patient characteristics (Table 20), quality assessments (Table 21), BMI data at longest followup (Table 22), and BMI data at specific timepoints (Table 23).

Laparoscopic Adjustable Gastric Banding (LAGB). Five of seven LAGB studies reported BMI data that met inclusion criteria. All five studies reported BMI data at the longest follow-up timepoint, and three studies also reported data specifically at specific post-surgery timepoints (one year data for three studies, two-year data for one study, and three-year data for one study).

For longest follow-up BMI, the length of followup in the five studies ranged from 1.7 to 3.3 years. Our study quality assessments indicated that four studies were of Moderate quality, and one study was of Low quality. The results are displayed graphically in Figure 5 below. Points to the left of center indicate BMI units lost at one or more years after surgery, whereas points to the right of center indicate BMI units gained. All five studies found that weight loss was statistically and clinically significant. We performed a random-effects meta-analysis that confirmed this finding. To investigate the robustness of this finding, we performed six tests (see Appendix C). The analysis passed all six tests, indicating good robustness. The overall quality of the studies was moderate; therefore we rated the strength of the evidence as Moderate.

For one-year BMI, all three studies found statistically and clinically significant weight loss. The data were rated as Moderate quality for all three studies, and all six qualitative robustness tests analyses were passed; therefore the strength of this evidence was also Moderate. The evidence for longer timepoints did not permit conclusions because there was no more than one study for any single longer timepoint (i.e., lack of replication of study findings).

The evidence did not permit precise quantitative estimates of the amount of BMI units lost after LAGB, because only two of five studies (40%) reported sufficient information for us to calculate the pre-post correlation for BMI. Such information is necessary to permit accurate effect size estimates of weight change after surgery.

Roux-en-Y Gastric Bypass (RYGB). Five of six RYGB studies reported BMI data that met inclusion criteria. All five studies reported BMI data at the longest follow-up timepoint, and three studies also reported data specifically at specific post-surgery timepoints (one year data for three studies, two-year data for one study, three-year data for one study, four-year data for one study, and five-year data for one study).

For longest follow-up BMI, the length of followup in the five studies ranged from 1 to 6.3 years. Our study quality assessments indicated that three studies were of Low quality, and two studies were of Moderate quality. The results are displayed graphically in Figure 6. All five studies found that weight loss was statistically and clinically significant. We performed a random-effects meta-analysis that confirmed this finding. To investigate the robustness of this finding, we performed six tests (see Appendix C). The analysis passed all six tests, indicating good robustness. The overall quality of the studies was low, therefore we rated the strength of the evidence as Weak.

For one-year BMI, all three studies found statistically and clinically significant weight loss. Two studies' data were of Moderate quality, and one study was of Low quality (thus the overall quality was Moderate). All six qualitative robustness tests analyses were passed, therefore the strength of this evidence was Moderate. The evidence for longer timepoints did not permit conclusions due to a lack of replication.

The evidence did not permit precise quantitative estimates of the amount of BMI units lost after RYGB, because only one of five studies (20%) reported sufficient information for us to calculate the correlation between pre-surgical and post-surgical BMI.

Vertical Banded Gastroplasty (VBG). Only one of three VBG met inclusion criteria for BMI data (the low-quality Mason study). Due to the lack of replication, the evidence was insufficient to permit conclusions about weight loss after VBG.

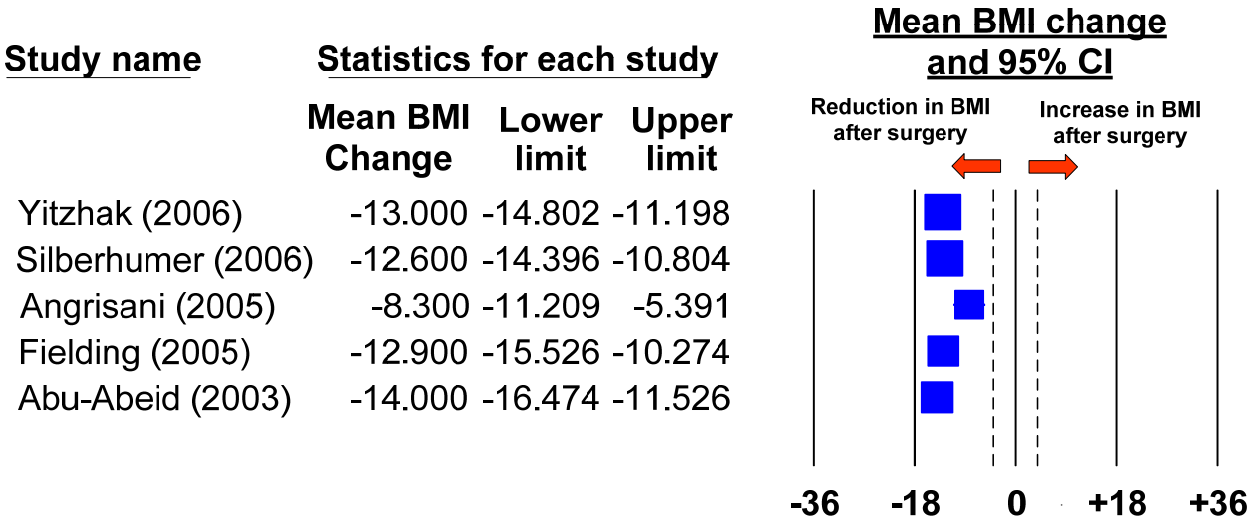
Combined VBG-RYGB. The single study of this procedure did meet inclusion criteria for BMI data, but it was of low quality. As above, a single low-quality study does not provide a sufficient basis for evidence-based conclusions.

Specific Age Groups (18-21, 13-17, 12 or Less)

The evidence was insufficient to permit conclusions for any specific age group (18-21, 13-17, ≤12) for any procedure. No studies enrolled only patients aged 18-21 or only patients aged 12 or less (refer again to Figure 3 on page 28). Four studies enrolled only patients aged 13-17, but only two studies' BMI data met inclusion criteria (the moderate-quality Strauss study of RYGB, and the low-quality Capella study of combined VBG-RYGB). Considering the lack of replication for

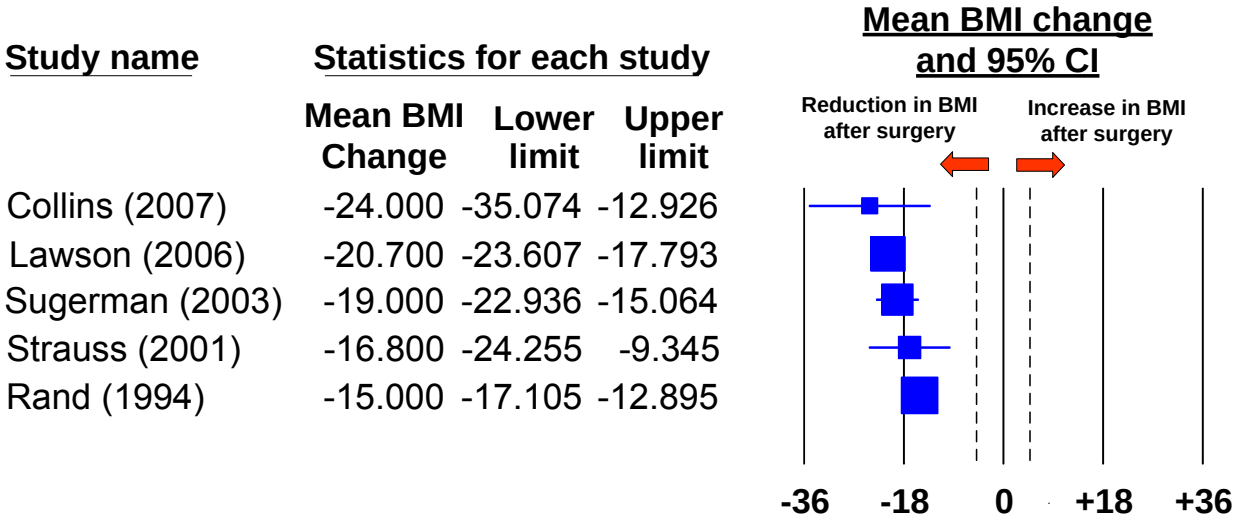
any single procedure in the 13-17 age group, and the moderate/low quality, the evidence was insufficient to permit conclusions.

Figure 5. Weight Loss After LAGB (at Longest Followup)



Note: The dashed lines represent a BMI change of 3.5 units, which corresponds to approximately 7% of body weight in the LAGB patients, and was used as the definition of clinically significant weight loss for LAGB patients. The average BMI prior to LAGB was approximately 45. The specific pre-surgical and post-surgical BMI data to produce this plot appear in Table 22 of Appendix E (page 107).

Figure 6. Weight Loss After RYGB (at Longest Followup)



Note: The dashed lines represent a BMI change of 4 units, which corresponds to approximately 7% of body weight in the RYGB patients, and was used as the definition of clinically significant weight loss for RYGB patients. The average BMI prior to RYGB was approximately 52. The specific pre-surgical and post-surgical BMI data to produce this plot appear in Table 22 of Appendix E (page 107).

Key Question 2: Does bariatric surgery for patients a-d (as above) improve co-morbid conditions linked to obesity (e.g., diabetes, hypertension, obstructive sleep apnea, musculoskeletal disorders), quality of life, or survival, as compared to non-operative approaches?

ECRI Institute evidence assessments:

- **Laparoscopic Adjustable Gastric Banding (LAGB) for morbidly obese patients aged 21 or less does resolve co-morbid conditions linked to obesity (hypertension, dyslipidemia, asthma) compared to non-operative approaches. Strength of evidence: Weak.**
- **Roux-en-Y Gastric Bypass for morbidly obese patients aged 21 or less does resolve co-morbid conditions linked to obesity (hypertension, sleep apnea) compared to non-operative approaches. Strength of evidence: Weak.**
- **The evidence is insufficient to permit quantitative estimates of the likelihood of comorbidity resolution, quality of life, or survival after any bariatric surgical procedure for pediatric patients.**
- **The evidence is insufficient to permit any conclusions about comorbidity resolution after other bariatric surgical procedures for pediatric patients.**
- **The evidence is insufficient to permit any conclusions about comorbidity resolution in specific age groups (18-21, 13-17, 12 or less)**

Patients Aged 21 or Less

The sections below describe the details of our analyses, separately for each bariatric surgical procedure. The comorbidity data for this Key Question appear in Table 24 of Appendix E (page 111), and the quality of life data appear in

dy		Diabetes	Hypertension	Dyslipidemia[b]	Sleep Apnea	Asthma	GERD	Musculoskeletal[c]	Notes
dies of Laparoscopic Adjustable Gastric Banding (LAGB)									
nak 06)(67)	Baseline N	2	3	-	10	3	-	-	-
	Resolved %	100% (2/2)	100% (3/3)	-	100% (10/10)	100% (3/3)	-	-	-
erhumer 06)(68,69)	Baseline N	5	12	4	-	3	1	8	3 cholelithiasis
	Resolved %	80% (4/5)	50% (6/12)	100% (4/4)	-	100% (3/3)	100% (1/1)	38% (3/8)	100% resolution for cholelithiasis. Cases that improved b not resolved included one for diabetes, six for hypertens and five for musculoskeletal problems.
ding 05)(71-73)	Baseline N	2	2	-	1	-	-	1	-
	Resolved %	100% (2/2)	100% (2/2)	-	100% (1/1)	-	-	100% (1/1)	-
gan 05)(74)	Baseline N	-	-	-	-	-	-	2	Also, two patients had heartburn without GERD.
	Resolved %	-	-	-	-	-	-	100% (2/2)	Heartburn outcomes not reported
-Abeid 03)(75)	Baseline N	-	-	3	-	-	-	-	1 Heart failure and pulmonary hypertension; 3 recurrent boil, 2 skin rashes; 7 stretch marks; 2 amenorrhea;1 cholelithiasis; offensive body odor and unpleasant appearance.
	Resolved %	-	-	67% (2/3)	-	-	-	-	Heart failure, pulmonary hypertension, and amenorrhea resolved; others not reported
dies of Roux-en-Y Gastric Bypass (RYGB)									
ns 07)(76,77)	Baseline N	6	6	7	2	4	1	8	4 depression/anxiety; 5 fatty liver/steatosis; 1 hepatomegaly; 2 hypothyroidism; 1 migraines; 3 polycystic ovarian syndrome; 2 iron deficiency anemia 1 gynecomastia; and 1 insulin resistance
	Resolved %	50% (3/6)	50% (3/6)	NR	0% (0/2)	NR	NR	NR	Cases that improved but not resolved included 3 for hypertension, two for diabetes, and two for sleep apnea cases. 2 out of 3 polycystic ovarian syndrome improved; other comorbidities not reported
son	Baseline N	-	-	-	10[a]	-	-	-	-

	Resolved %	-	-	See notes	100% (10/10)	-	-	-	For dyslipidemia, study did not report resolution or improvement rates, but instead reported overall statistica significant postoperative improvements in triglyceride, total cholesterol, fasting blood glucose, and fasting insuli
erman 03)(35)	Baseline N	2	11	-	6	-	5	11	3 pseudotumor cerebri; 3 polycystic ovarian syndrome
	Resolved %	100% (2/2)	82% (9/11)	-	100% (6/6)	-	60% (3/5)	36% (4/11)	100% resolution in the 3 cases of pseudotumor cerebri a also in the 3 cases of polycystic ovarian syndrome
uss 01)(36)	Baseline N	-	3	-	2	-	-	1	1 progressive dyspnea on exertion; obesity-hypoventilati syndrome1; 1 refusing to attend school because of teasi
	Resolved %	-	100% (3/3)	-	100% (2/2)	-	-	NR	The patient reentered school; other comorbidities not reported
dies of Vertical Banded Gastroplasty (VBG)									
enstein 05)(81)	Baseline N	-	2	-	1	-	-	-	-
	Resolved %	-	NR	-	100% (1/1)	-	-	-	-

[a] Sleep apnea outcomes reported by a secondary publication.(78)
[b] Dyslipidemia includes those reported as dyslipidemia, hyperglyceridemia and hypercholesterolemia
[c] Reported musculoskeletal conditions included those reported as orthopedic problems, osteoarthropathy, joint and musculoskeletal complaints, degenerative joint disease. back pain, arthralgia, and vertebra fractures

GERD Gastroesophageal reflux disease
NR or – indicate that the study did not report any patient outcomes for this comorbidity

Table 25 of Appendix E (page 111).

Laparoscopic Adjustable Gastric Banding (LAGB). Three of seven LAGB studies met inclusion criteria for comorbidity and quality of life outcomes.(67,68,75) A summary of the data appears in Table 5 below. All three studies were of Moderate quality. For each of three comorbidities (hypertension, dyslipidemia, and asthma), data were reported by two of the three studies. The pertinent outcomes were:

- Resolution of hypertension: 50% (6/12) and 100% (3/3),
- Resolution of dyslipidemia: 67% (2/3) and 100% (4/4),
- Resolution of asthma: 100% (3/3) and 100% (3/3)

These are large reductions, but due to the moderate quality and limited quantity, we rated the strength of evidence as Weak for these outcomes. For all other outcomes (diabetes, sleep apnea, GERD, musculoskeletal problems, quality of life), there was only one LAGB study reporting the data, so the evidence was insufficient to permit conclusions.

Roux-en-Y Gastric Bypass (RYGB). Four of six RYGB studies reported comorbidity data that met inclusion criteria. A summary of the data appears in Table 5 below. All four studies were of Moderate quality. Three of the four studies reported hypertension resolution,(35,36,76) and two of the four studies reported resolution of sleep apnea.(35,78) The pertinent outcomes were:

- Resolution of hypertension: 50% (3/6), 82% (9/11), and 100% (3/3)
- Resolution of sleep apnea: 100% (10/10) and 100% (6/6)

Again, these are large reductions, but due to the moderate quality and limited quantity, we rated the strength of evidence as Weak for these outcomes. For all other comorbidities (diabetes,

dyslipidemia, asthma, GERD, musculoskeletal problems), there was only one RYGB study reporting the data, so the evidence was insufficient to permit conclusions.

Specific Age Groups (18-21, 13-17, 12 or Less)

Only one study (the Strauss study) enrolled a specific age group and was also included for comorbidity data. Due to the lack of replication of this moderate-quality study, the evidence was insufficient to permit conclusions.

Table 5. Summary of Results of Comorbidity Resolution

Bariatric procedure	Comorbidity	Diabetes	Hypertension	Dyslipidemia	Sleep Apnea	Asthma	GERD	Musculoskeletal	Other
Laparoscopic Adjustable Gastric Banding (LAGB)	Amount of Evidence[a]	1 study, 5 patients	2 studies, 15 patients	2 studies, 7 patients	1 study, 10 patients	2 studies, 6 patients	-	1 study, 8 patients	1 study, 3 patients[b]
	% Resolved	80%	50%-100%	67%-100%	100%	100%	-	38%	100%[b]
Roux-en-Y Gastric Bypass (RYGB)	Amount of Evidence[a]	1 study, 6 patients	3 studies, 20 patients	-c	2 studies, 16 patients	-	1 study, 5 patients	1 study, 11 patients	1 study, 3 patients[d]
	% Resolved	50%	50%-100%	-c	100%	-	60%	36%	100%[d]
Vertical Banded Gastroplasty (VBG)	Amount of Evidence[a]	-	-	-	-	-	-	-	-
	% Resolved	-	-	-	-	-	-	-	-
Combined RYGB-VBG	Amount of Evidence[a]	-	-	-	-	-	-	-	-
	% Resolved	-	-	-	-	-	-	-	-

Note: "-" indicates that there were no studies of this bariatric procedure that reported the postsurgical status of comorbidities for at least three patients who had the condition before surgery. The Barnett study of RYGB and VBG reported comorbidity resolution data, but these data were combined for three bariatric procedures, and therefore were excluded. Three other studies (the Fielding study of LAGB, the Horgan study of LAGB, and the Greenstein study of VBG) reported data for comorbidity resolution, but there were no more than 3 patients for any single comorbidity, so the data were excluded.

The data for individual studies appear in Table 24 in Appendix E.

[a] This row refers to the number of studies that had reported resolution results in at least 3 patients who had the condition before surgery (along with the combined number of patients with that condition at baseline). Some studies reported data on conditions with fewer than 3 patients, which did not meet our inclusion criteria.

[b] Cholecystitis

[c] The only study RYGB that reported results for dyslipidemia (the Lawson study) did not report in terms of resolution, but instead in terms of statistically significant postoperative improvements in triglyceride, total cholesterol, fasting blood glucose, and fasting insulin.

[d] 100% resolution for both pseudotumor cerebri and polycystic ovary syndrome.

Key Question 3: What are the relative safety profiles of bariatric surgery and non-operative approaches for patients aged a) 21 or less, b) 18-21, c) 13-17, and d) 12 or less?

ECRI Institute evidence assessments:

- **No perioperative mortality was reported across included studies.**
- **One late death was reported in a RYGB study; no late death was reported in other included studies.**
- **The overall reoperation rate for the LAGB cases was 9.39%; such reoperation rate was not available for the RYGB cases.**
- **The most frequently reported postoperative complication for LAGB was band slippage.**
- **The most frequently reported postoperative complication for RYGB was related to protein-calorie malnutrition and micronutrient deficiency.**
- **Potentially severe adverse events after RYGB included pulmonary embolism, severe malnutrition, immediate postoperative bleeding, gastrointestinal obstruction, and staple line leak. RYGB appeared to cause more postoperative complications than LAGB.**
- **The evidence is insufficient to permit any conclusions about whether bariatric surgery would have any negative impacts on growth and development of pediatric patients.**
- **The evidence is insufficient to permit any conclusions about potential harms in specific age groups (18-21, 13-17, 12 or less).**
- **Systematic reviews on pediatric obesity management did not provide sufficient data for the development of a safety profile of nonoperative approaches.**

Patients Aged 21 or Less

The sections below describe the details of our analyses, separately for each bariatric surgical procedure. The reported data for this Key Question appear in Table 26, Table 27, and Table 28 of Appendix E (starting on page 114).

Laparoscopic Adjustable Gastric Banding (LAGB). All seven LAGB studies (10 publications) reported adverse events that met the inclusion criteria. For this Key Question, six studies(61,67-74) were rated as Moderate quality; the remaining one(75) was rated as Low quality. The surgical procedures reported in the studies were performed between 1996 and 2006. All but one study(61) had an average postoperative follow-up time longer than 12 months. At individual case level, follow-up time in all studies ranged from 1 to 85 months.

Reported adverse events are summarized in Table 6 below. No perioperative or late mortality was reported by any study. Twenty-six reoperations were performed to correct various complications. The overall reoperation rate was 9.39%. Band slippage was the most frequently reported post-LAGB complication, which occurred on 12 (4.3%) of the 277 patients. Eight of the 12 cases occurred in one center using SAGB, while the other four cases occurred in three centers

using LAP-BAND. In addition, eight cases of iron deficiency and five cases of mild hair loss were reported among the 277 patients. The case numbers of other reported adverse events were equal to or less than three.

Roux-en-Y Gastric Bypass (RYGB). Six RYGB studies reported adverse events that met inclusion criteria. For this Key Question, all but one study were rated as Moderate quality; Rand's study(37) was rated as Low quality. The surgical procedures reported in the studies were performed between 1978 and 2005. Average postoperative follow-up time of the studies ranged from less than one year to 6 years. At individual case level, follow-up time ranged from 2 weeks to 6 years.

The adverse events reported in the studies are summarized in Table 6 below. No perioperative death was reported in the studies. However, one late death (occurred 30 days after surgery) was reported in Lawson's study.(66,78,79) The patient initially presented with hypercholesterolemia, hyperinsulinemia, hypertension, sleep apnea, and degenerative joint disease at a BMI of 80 kg/m^2 and weight of 630 lb. After an initial uncomplicated 3-month postoperative course, the patient developed severe infectious colitis because of *Clostridium difficile*. Severe diarrhea and extended period of profound hypovolemia associated with the colitis resulted in multiorgan failure and subsequent death 9 months after RYGB. In addition, one patient in Barnett's study(65) died 4 years after surgery and two patients in Sugerman's study(35) died 2 years and 6 years after surgery of causes that were unlikely to be directly related to the bariatric surgeries.

Although the RYGB studies had a smaller patient pool, they had a longer list of postoperative complications than LAGB studies. Some life-threatening complications, such as shock, pulmonary embolism, severe malnutrition, immediate postoperative bleeding, gastrointestinal obstruction, and staple line leak were reported in the RYGB studies. The problems related to protein-calorie malnutrition and micronutrient deficiency were the most frequently reported complications after RYGB. Inconsistencies in data reporting among the six studies prevented a calculation of a combined reoperation rate for RYGB.

Specific Age Groups (18-21, 13-17, 12 or Less)

No study included for the Key Question enrolled only patients aged 18-21 or only patients aged 12 or less. One LAGB study(61) and two RYGB studies(36,65) enrolled only patients aged 13-17. Other studies all reported outcomes for mixed age groups. The evidence was insufficient to permit any conclusions about potential harms in specific age groups (18-21, 13-17, 12 or less).

Table 6. Reported Postoperative Adverse Events for LAGB and RYGB

LAGB	RYGB
Number of studies: 7 **Total number of patients**: 277 **Reported adverse events (number of events):** Band-related events: • Band slippage (12) • Intragastric migrations (3) • Port/tubing problems (2) Other events: • Gastric pouch dilatation (2) • Hiatal hernia (2) • Wound infection (1) • Gastroesophageal reflux (1) • Nephrolithiasis and cholelithiasis (2) • Iron deficiency (8) • Mild hair loss (5) **Number of reoperations:** 26[a] **Reported perioperative deaths**: 0 **Reported late deaths**: 0	**Number of studies**: 6 **Total number of patients**: 125[b] **Reported adverse events (number of events)**: • Protein-calorie malnutrition and micronutrient deficiency including iron deficiency ,vitamin deficiency , hypokalemia, hypoglycemia, and beriberi (16) • Dumping syndrome (≥3) • Dehydration (≥1) • Shock (≥1) • Pulmonary embolism (1) • Deep vein thrombosis (≥1) • Small bowel obstruction (2) • Food obstruction (≥2) • Stomal stenoses (3) • Anastomotic stricture/gastrojejunostomy stricture (≥1) • Pouch dilation (5) • Marginal ulcer (6) • Staple line leak (≥1) • Immediate postoperative bleeding (1) • Gastrostomy revision (≥1) • Incisional hernia (7) • Internal hernia (≥1) • Wound infection (≥6) • Cholecystectomy (6) • Melena (≥1) • Other complains including nausea and diarrhea (≥2) **Number of reoperations:** Not summarizable[c] **Reported perioperative deaths**: 0 **Reported late deaths**: 1[d]

[a] Reoperations were performed to correct postoperative complications including band slippage, gastric dilation, intragastric band migration, psychological intolerance of band, hiatal hernia, cholecystitis, and tubing crack. See Table 26 in Appendix E (page 114).
[b] Among the 142 patients in the six studies, only 125 received RYGB procedures.
[c] Inconsistencies in data reporting among the six studies prevented a calculation of a combined reoperation rate for RYGB.
[d] One patient died 9 months after RYGB in Lawson's study.(66,78,79) The one death in Barnett's study (65) and the two deaths in Sugerman's study (35) were not counted because the causes of death were unlikely to be directly related to the bariatric surgeries.

Safety Profile of Nonoperative Approaches

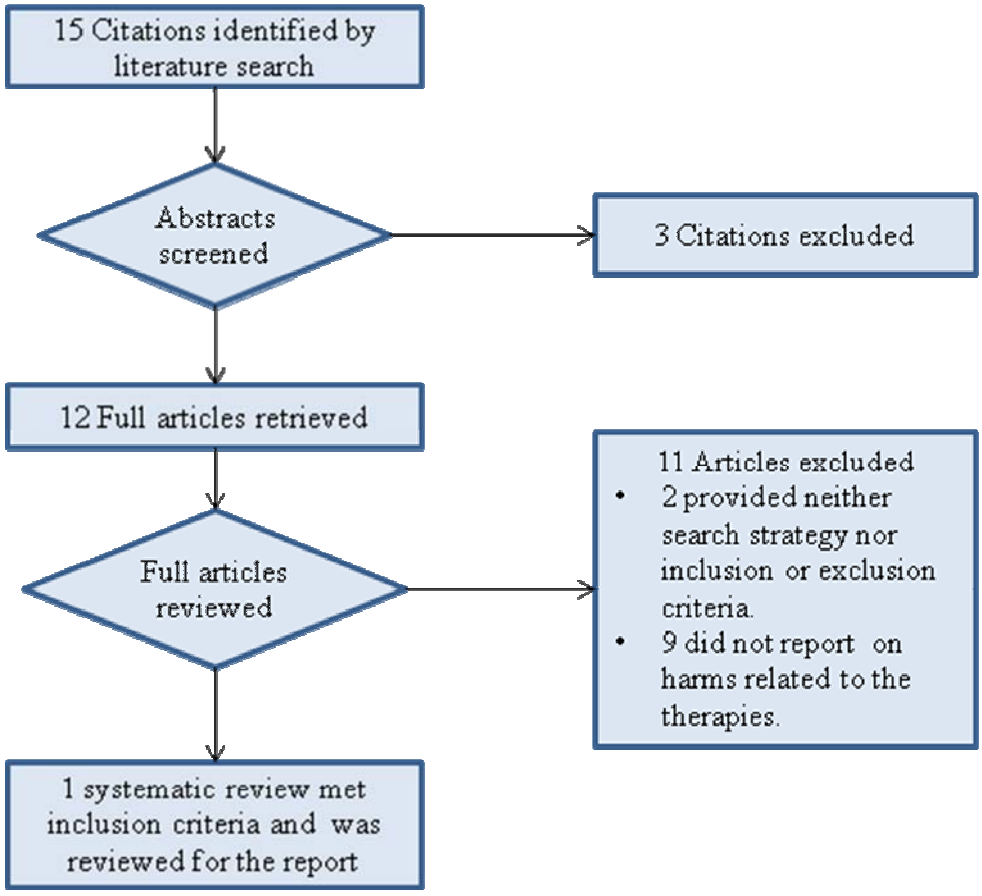
We searched four electronic sources (Medline, PsycINFO, EMBASE, and CINAHL) on April 19, 2007 and also conducted a manual search for systematic reviews on nonoperative approaches to pediatric obesity management. Search results are depicted in Figure 7 below.

Our searches identified one systematic review that met our inclusion criteria(86), which we rated as High in quality using the AMSTAR tool. This evidence report for the U.S. Preventive Services Task Force (USPSTF) assessed adverse events associated with behavioral counseling interventions, pharmacotherapy, and surgical treatments for overweight. Diet therapy and physical exercise were not addressed. Examples of adverse events reported on include stigmatization, binging or purging behaviors, eating disorders, suppressed growth, or exercise-induced injuries.

With behavioral counselling, potential eating problems or weight management behaviors were the only harms addressed in the two trials (n = 91) included in the USPSTF report. One trial reported no adverse effects on problematic eating after primary care-based comprehensive behavioral treatment in 37 of 44 adolescent trial completers. The other trial reported no effect on eating disorder symptoms, weight dissatisfaction, or purging/restricting behaviors in 47 8-12 year-olds in a family-based comprehensive behavioral treatment program.http://www.ahrq.gov/clinic/uspstf05/choverwt/chovsum2.htm - ref95 The USPSTF report only included one trial (n = 43) that reported on the potential harms of pharmacotherapy. In the placebo-controlled phase of this sibutramine trial, 44% (19/43) of patients in the active medication group reduced or discontinued the medication due to elevated blood pressure, pulse rate, or both.

Our search of systematic reviews did not yield sufficient results for building a comprehensive safety profile for nonsurgical approaches to obesity management. To achieve this goal, several separate evidence reports may need to be done on different diet therapies, physical exercise programs, behavioral therapy, and weight-loss medications (e.g., orlistat and sibutramine).

Figure 7. Systematic Review Attrition Diagram



Key Question 4: What are the relative cost profiles of bariatric surgery and non-operative approaches for patients aged a) 21 or less, b) 18-21, c) 13-17, and d) 12 or less?

ECRI Institute evidence assessments:

- **In 2004, the median hospital inpatient cost for pediatric bariatric surgery was $8,651; the median hospital inpatient charge was $25,021.**
- **No significant difference in hospital inpatient cost or charge was found between the 13-17 and the 18-21 age groups in 2004. No conclusions can be drawn regarding the cost or charge of patients aged less than 12 due to lack of data.**
- **We estimated that the total three-year cost of a pediatric LAGB procedure without major postoperative complications is $11,628 in 2007. This total cost contains a cost of $2,793 for postoperative care in the first three years after surgery.**
- **We estimated that the total three-year cost of a pediatric RYGB procedure (open approach) without major postoperative complications is $14,125 in 2007. This total cost contains a cost of $2,653 for postoperative care in the first three years after surgery.**
- **Data were not sufficient to permit a comparison of cost between the State of Washington and the nation.**
- **The evidence was not sufficient to permit the development of a comprehensive cost profile of nonoperative approaches to pediatric obesity management.**

The sections below describe the details of our cost analyses. The first four sections describe hospital inpatient cost, professional service fees, three-year postoperative care cost, and the syntheses of the costs using two scenarios. The last section describes the cost of nonoperative approaches to pediatric obesity management.

Hospital Inpatient Cost

Using the HCUP NIS 2004 data, we identified a total of 415 pediatric (patients age 21 or younger) bariatric surgery cases in the 20% stratified sample. Table 7 is a summary of these cases. Three hundred and forty-two (82.41%) of the pediatric cases were in the 18-21 age group, while the remaining 73 (17.59%) cases were in the 13-17 age group. No patients aged 12 years or younger were identified in the data set.

Of all pediatric cases, 412 (99.3%) had morbid obesity as the primary diagnosis; the remaining three cases had morbid obesity as the second, third, or sixth diagnosis. Over sixty percent of all pediatric cases had ICD-9 code 44.39 (gastroenterostomy including bypass other than high gastric bypasses) as the primary procedure code, followed by 17 percent having ICD-9 code 44.31 (high gastric bypass) and 10 percent with ICD-9 code 44.38 (laparoscopic bypass) as the primary procedure code.

Table 8 is an overview of the inpatient charge and cost for the pediatric bariatric surgery cases. The median inpatient hospital charge is $25,021, whereas the mean charge is $30,594. The median cost is $8,651, with the mean cost being $10,913. The mean values of charge and cost were nearly 3 times as high as the median values (Figure 8). The significant discrepancies

between the mean and the median values as well as the statistics indicated that the charge and cost data distributions were positively skewed. Therefore, median values were the better measures of central tendency than mean values for inpatient charge and cost.

Table 9, Figure 9, and Figure 10 provide an overview of inpatient charge and cost by age group. No results were obtained regarding the cost or charge of patients aged less than 12 due to lack of data. No statistically significant difference was found either in the mean cost or charge between the 13-17 and the 18-21 age groups (p >0.10).

Table 10, Figure 11, and Figure 12 provide an overview of inpatient charge and cost by procedure. The median and mean charges for the restrictive procedure category are $20,051 and $22,758 respectively, compared to $26,150 and $31,853, respectively for the bypass procedure category. The median and mean costs for the restrictive procedures are $6,688 and $7,899 respectively, compared to $8,893 and $11,276, respectively for the bypass procedures.

Table 11 is an overview of inpatient charge for the pediatric bariatric procedures performed in the State of Washington in 2002-2004. Using the same ICD-9 codes combinations that we used with the NIS 2004 data set, we only identified 14, 25 and 15 pediatric bariatric surgery cases, respectively for 2002, 2003 and 2004 in the SID (WA) data sets. We were unable to obtain the inpatient cost data for the State because the file containing the cost-to-charge ratios could not be linked directly to the file containing the charge data in the SID (WA) datasets. Figure 13 shows that the inpatient charge (both the median and the mean) rose slightly from 2002 to 2004. In 2004, the median and mean inpatient charges were $21,688 and $26,483, respectively in the State of Washington, compared to $25,021 and $30,594, respectively for the nation. The small case number did not permit a meaningful analysis of charge data by age group or procedure for the State.

Table 7. Summary of Pediatric Bariatric Surgery Cases in NIS 2004 (20% Sample)

	Number of Patients	Percentage
Age		
<13	0	0
13-17	73	17.6
18-21	342	82.4
Total	415	100.0
Primary Diagnosis (ICD-9 Codes)		
Morbid obesity (278.01)	412	99.3
Other hyperalimentation (278.8)	1	.2
Digestive system complications (997.4)	1	.2
Complications due to implant or internal device (996.59)	1	.2
Total	415	100.0
Primary Procedure (ICD-9 Codes)		
Other gastroenterostomy (bypass) (44.39)	255	61.4
High gastric bypass (44.31)	71	17.1
Laparoscopic gastroenterostomy (bypass) (44.38)	44	10.6
Other operation on stomach (44.69)	30	7.2
LAGB (44.95)	11	2.7
Laparoscopic gastroplasty (vertical banding) (44.68)	3	.7
Small-to-small intestinal anastomosis (45.91)	1[a]	.2
Total	415	100.0

[a] The case had ICD-9 Code 44.69 as one of the five secondary procedure codes.

Table 8. Overview of Inpatient Charge and Cost, 2004

		Charges	Cost
N		415	391[a]
Mean		$30,594	$10,913
Median		$25,021	$8,651
Skewness		4.471	3.239
Standard error of skewness		0.120	0.123
Percentiles	25	$19,182	$6,976
	75	$37,390	$12,379

[a] Both hospital-specific and group average CCRs were missing for 24 of the 415 cases.

Figure 8. Median Inpatient Cost and Charge, 2004

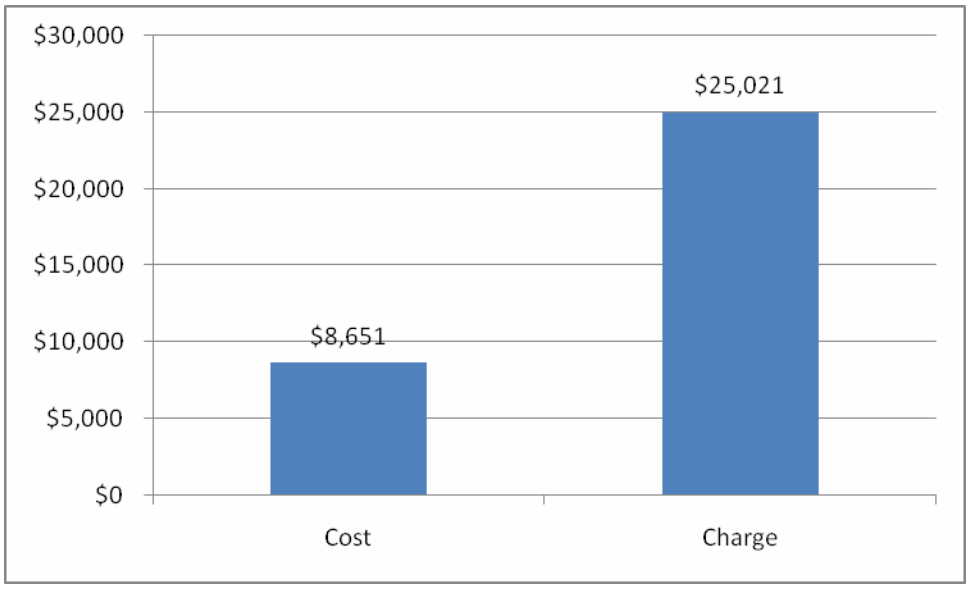


Table 9. Inpatient Charge and Cost by Age Group, 2004

Age		Charge			Cost		
		Case number (%)	Median	Mean[a]	Case number (%)	Median	Mean[a]
≤21		415	$25,021	$30,594	391[b]	$8,651	$10,913
	≤12	0	N/A	N/A	0	N/A	N/A
	13-17	73 (17.59%)	$23,311	$29,867	65 (16.62%)	$7,973	$9,873
	18-21	342 (82.41%)	$25,161	$30,749	326 (83.38%)	$8,945	$11,121

[a] p >0.10 for 13-17 group vs. the 18-21 group
[b] Both hospital-specific and group average CCRs were missing for 24 of the 415 cases.

Table 10. Inpatient Charge and Cost by Procedure, 2004

Procedure		Charge			Cost		
		Case number	Median	Mean	Case number	Median	Mean
Bypass Procedures		370	$26,150	$31,547	349	$8,893	$11,276
	Open	245	$26,152	$31,853	235	$9,179	$11,463
	Laparoscopic	125	$26,147	$30,946	114	$8,634	$10,892
Restrictive Procedures		45	$20,051	$22,758	42	$6,688	$7,899
	Open	22	$19,220	$21,086	21	$6,180	$7,004
	Laparoscopic	23	$20,624	$24,358	21	$7,178	$8,793

Figure 9. Median Inpatient Charge by Age Group, 2004

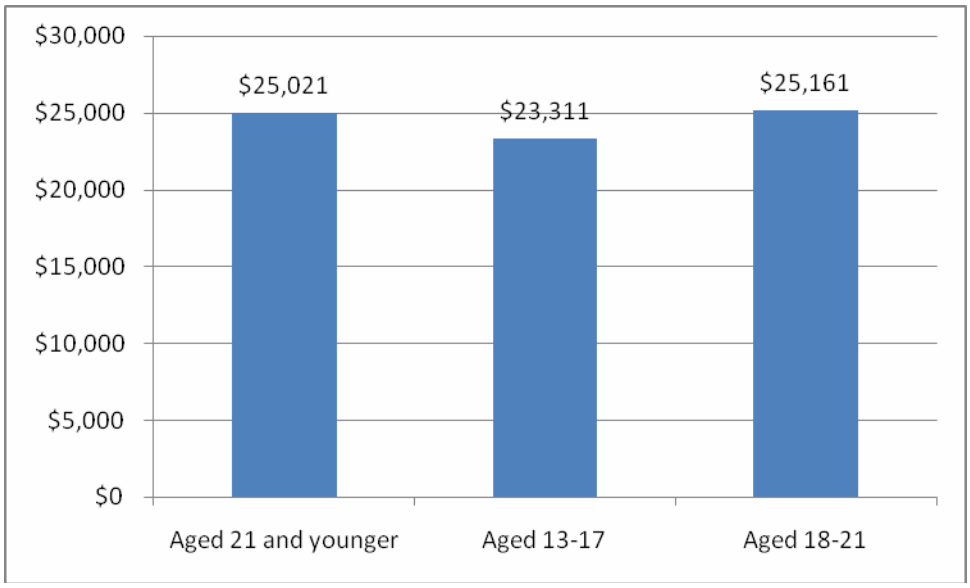


Figure 10. Median Inpatient Cost by Age Group, 2004

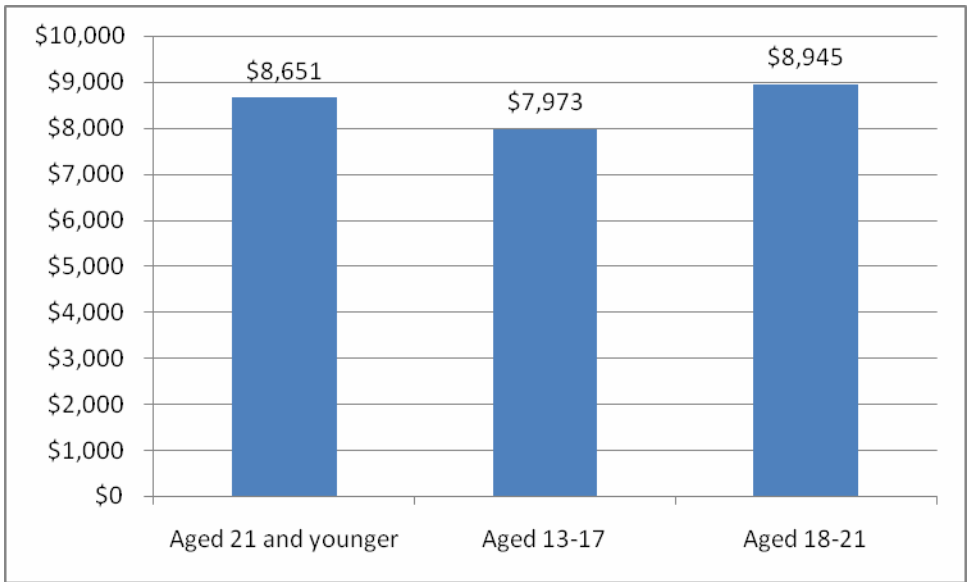


Figure 11. Median Inpatient Charge by Procedure, 2004

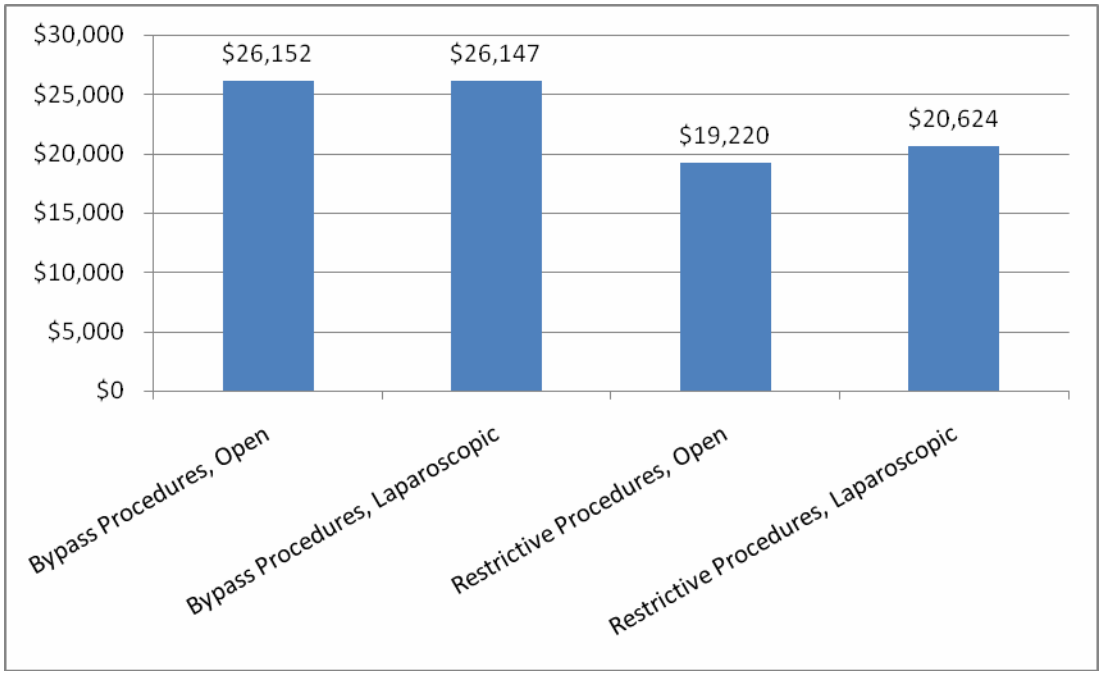


Figure 12. Median Inpatient Cost by Procedure, 2004

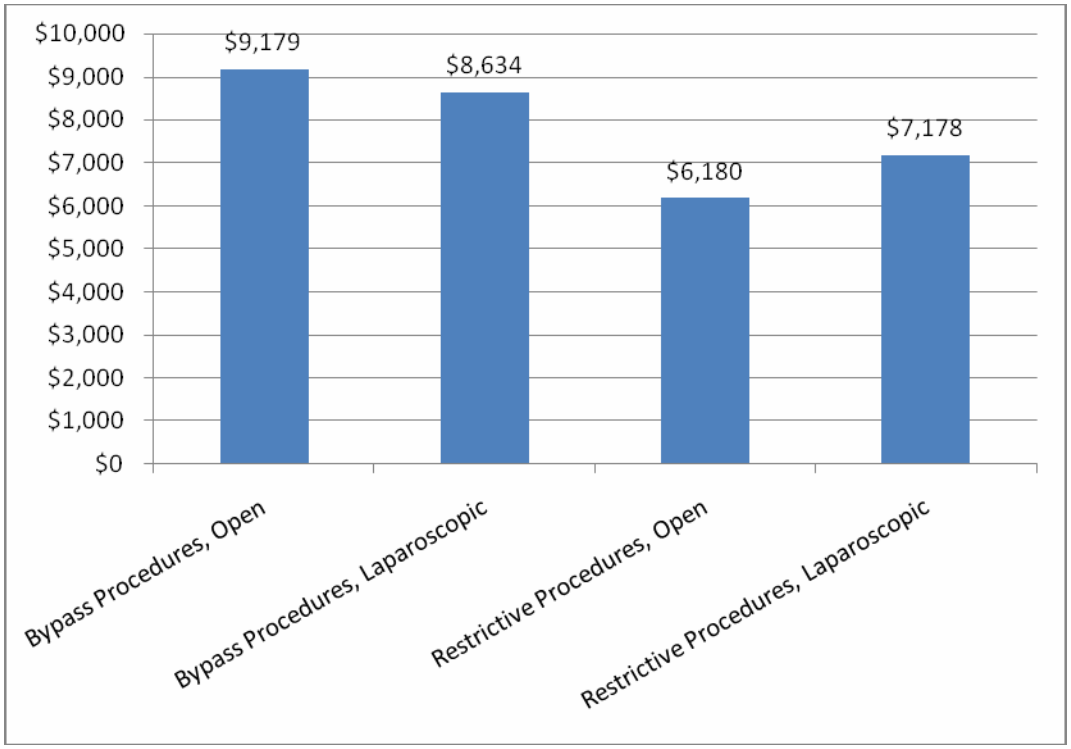
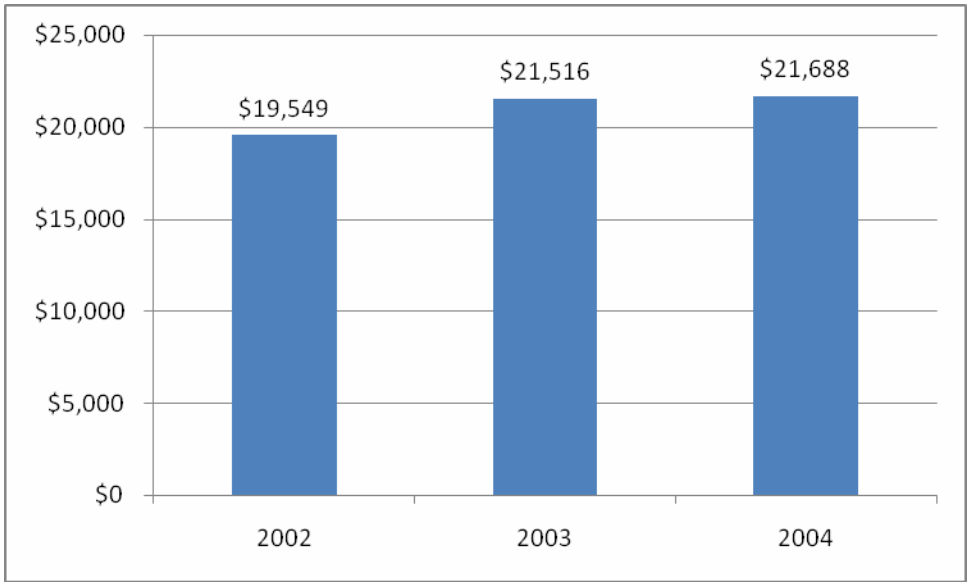


Table 11. 2002-2004 Inpatient Charge, Washington State

Year	Case number	Median	Mean
2004	15	$21,688	$26,483
2003	25	$21,516	$22,143
2002	14	$19,549	$20,494

Note: Charge amounts are all in 2004 dollars

Figure 13. 2002-2004 Median Inpatient Charge, Washington State



Note: Charge amounts are all in 2004 dollars.

Cost of Professional Services

Table 12 is a summary of the Healthcare Common Procedure Coding System (HCPCS) codes and the Medicare physician fee amounts for bariatric surgeries in 2007. For each surgery, we listed the Medicare national average payment, as well as the geographically adjusted payments for the two regions in the State of Washington. Across the procedures, the payments for the Seattle region are higher than the national averages, but the payments for the rest of Washington State are lower than the national averages. Although these listed MPFS fees reflect the charge amounts rather than the true costs, we believe that they are good proxy measures of the true costs due to the reasons that we discussed in the *Methods* section.

Table 12. Medicare Professional Fee Schedule for Bariatric Surgeries, 2007

HCPCS Code[a]	Code Description	Medicare Payment[b]			Procedure
		National	Seattle, WA	Rest of WA	
RYGB procedures					
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy	$1429.11	$1469.09	$1397.94	RYGB, open
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)	Not available	$1578.09	$1500.53	RYGB, laparoscopic
LAGB-related procedures					
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band (gastric band and subcutaneous port components)	$981.17	$1012.06	$959.18	LAGB
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric band component only	$1121.39	$1155.13	$1096.12	See code description
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band component only	$844.74	$869.73	$825.69	See code description
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric band component only	$1121.77	$1155.44	$1096.42	See code description
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band and subcutaneous port components	$848.53	$874.88	$829.96	See code description
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only	$284.99	$301.39	$280.72	See code description
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only	$270.21	$282.63	$264.31	See code description
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only	$386.18	$403.13	$378.13	See code description

HCPCS Code[a]	Code Description	Medicare Payment[b]			Procedure
		National	Seattle, WA	Rest of WA	
Restrictive procedures other than LAGB					
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty	Not available	$1120.51	$1066.88	VBG, open
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty	$1106.23	$1137.27	$1082.16	Gastric restrictive procedure other than VBG, open
Other procedures					
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption	$1571.61	$1614.30	$1537.08	Biliopancreatic bypass procedure (Scopinaro)
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)	$1706.90	$1749.11	$1668.42	Biliopancreatic bypass with duodenal switch
43999	Unlisted procedure, stomach	Not available	Not available	Not available	Long- limb gastric bypass (>100 cm) (which has no specific code.
43659	Unlisted laparoscopy procedure, stomach	Not available	Not available	Not available	Mini-gastric bypass (which has no specific code)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption	$1650.06	$1698.29	$1614.96	See code description
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric band (separate procedure)	$1700.46	$1746.30	$1662.92	See code description

[a] The coding information regarding bariatric surgeries was from Wellmark Blue Cross and Blue Shield, available at http://www.wellmark.com/e_business/provider/medical_policies/policies/obesity_surgery.htm, accessed on May 2, 2007.

[b] The HCPCS code and Medicare payment information was from the CMS Web site, available at http://www.cms.hhs.gov/apps/ama/license.asp?file=/pfslookup/02_PFSsearch.asp, accessed on May 2, 2007.

Postoperative Care Costs

Table 13 is a summary of the HCPCS codes and the Medicare payment amounts for various postoperative professional services and tests. Again, these amounts reflect the charges rather than the true costs for the services. They are only used as the proxy measures of the costs for the services. The total postoperative care cost for the first three years will be presented in the next section in two scenarios we created.

Table 13. HCPCS Codes and Medicare Fees for Bariatric Surgery Follow-up Care, 2007

HCPCS Code	Service/Test	Medicare Payment[a]
99211-99215	Office/outpatient visit, established patients	$20.09-$120.03
90806	Individual psychotherapy, insight oriented, behavior modifying, and/or supportive, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient	$89.82
97802	Medical nutrition therapy; reassessment and intervention, individual, face-to-face with the patient, each 15 minutes	$27.29
S2083	Adjustment of gastric band diameter	Not available[b]
93000	Electrocardiogram, complete	$24.63
80048	Basic metabolic panel	$11.83
80051	Electrolyte panel	$9.80
80076	Hepatic function panel	$11.42
84550	Assay of blood/uric acid	$6.31
80061	Lipid panel	$18.72
82746	Blood folic acid serum	$20.54
84466	Assay of transferrin	$17.84
83540	Assay of iron	$9.05
81001	Urinalysis, auto w/scope	$4.43
83036	Glycosylated hemoglobin test (hemoglobin A1c)	$13.56
82962	Glucose blood test	$3.27
83525	Assay of insulin	$15.98
82951	Glucose tolerance test (GTT)	$17.99
84443	Assay thyroid stimulating hormone	$23.47
85027	Complete blood cell count, automated	$9.04

[a] For the laboratory tests, national limit amounts from the Medicare's Clinical Laboratory Fee Schedule are listed. For professional fees, non-facility prices from MPFS are listed.

[b] For S2083 (Adjustment of gastric band diameter), non national Medicare payment is available. We found the Blue Cross Blue Shield Texas paid $35 for the services in 2005. Data available at http://www.bcbstx.com/provider/pdf/prof_reimbursement/dftpe_200506_092005_full_secured.pdf, accessed on May 2, 2007.

Synthesis of Cost -Two Scenarios

In this section, costs of surgery and relevant postoperative care (the first three years) are synthesized together using the two scenarios we described in the *Methods* section.

Table 14 is a summary of the costs for the first scenario, in which a patient received LAGB and did not experience any costly postoperative complications. The cost for the surgical procedure alone is $8,835. The cost for postoperative care is $1,831 in the first years, $541 in the second year, and $422 in the third year. The total three-year cost for the scenario is $11,624.

Table 14. Cost of LAGB and Follow-up Care without Major Postoperative Complications

Services		Surgery cost	Postoperative care cost						Total Cost
			Unit Cost	Year 1		Year 2		Year 3	
				Frequency	Cost	Frequency	Cost	Frequency	Cost
Hospital inpatient care		7,854[a]							7,854
Professional services	Surgery	981							981
	Follow-up visits		59.50	12	714.00	4	238.00	2	119.00	1,071
	Band diameter adjustments		35.00	2	70.00	1	35.00	1	35.00	140
	Dietitian counseling		54.58	2	109.16					109
	Psychological evaluation		89.82	1	89.82					90
Lab tests	Basic metabolic panel		11.83	4	47.32	1	11.83	1	11.83	71
	Electrolyte panel		9.80	4	39.20	1	9.80	1	9.80	59
	Hepatic function panel		11.42	4	45.68	1	11.42	1	11.42	69
	Assay of blood/uric acid		6.31	4	25.24	1	6.31	1	6.31	3
	Lipid panel		18.72	4	74.88	1	18.72	1	18.72	112
	Blood folic acid serum		20.54	4	82.16	1	20.54	1	20.54	123
	Assay of transferrin		17.84	4	71.36	1	17.84	1	17.84	107
	Assay of iron		9.05	4	36.20	1	9.05	1	9.05	54
	Urinalysis, auto w/scope		4.43	4	17.72	1	4.43	1	4.43	27
	Glycosylated hemoglobin test		13.56	4	54.24	1	13.56	1	13.56	81
	Glucose blood test		3.27	4	13.08	1	3.27	1	3.27	20
	Assay of insulin		15.98	4	63.92	1	15.98	1	15.98	96
	Glucose tolerance test		17.99	4	71.96	1	17.99	1	17.99	108
	Assay thyroid stimulating hormone		23.47	4	93.88	1	23.47	1	23.47	141
	Complete blood cell count, automated		9.04	4	36.16	1	9.04	1	9.04	54
	Esophagram		74.66	1	74.66	1	74.66	1	74.66	224
Total		**8,835**			**1,831**		**541**		**422**	**11,628**

Note: Cost amounts are all in 2007 dollars.

[a] The number was derived from the 2004 value through a conversion using the Consumer Price Index developed by the U.S. Bureau of Labor Statistics.

Table 15 is a summary of the costs for the second scenario, in which a patient received RYGB through an open approach and did not experience any costly postoperative complications. The cost for the surgical procedure alone is $11,472. The cost for postoperative care is $1,761 in the first years, $506 in the second year, and $387 in the third year. The total three-year cost for the scenario is $14,125.

Table 15. Cost of Open RYGB and Follow-up Care without Major Postoperative Complications

Services		Surgery cost	Postoperative care cost							Total cost
			Unit Cost	Year 1		Year 2		Year 3		
				Frequency	Cost	Frequency	Cost	Frequency	Cost	
Hospital inpatient care		10,043[a]								10,043
Professional services	Surgery	1,429								1,429
	Follow-up visits		59.50	12	714.00	4	238.00	2	119.00	1,071
	Dietitian counseling		54.58	2	109.16					109
	Psychological evaluation		89.82	1	89.82					90
Lab tests	Basic metabolic panel		11.83	4	47.32	1	11.83	1	11.83	71
	Electrolyte panel		9.80	4	39.20	1	9.80	1	9.80	59
	Hepatic function panel		11.42	4	45.68	1	11.42	1	11.42	69
	Assay of blood/uric acid		6.31	4	25.24	1	6.31	1	6.31	38
	Lipid panel		18.72	4	74.88	1	18.72	1	18.72	112
	Blood folic acid serum		20.54	4	82.16	1	20.54	1	20.54	123
	Assay of transferrin		17.84	4	71.36	1	17.84	1	17.84	107
	Assay of iron		9.05	4	36.20	1	9.05	1	9.05	54
	Urinalysis, auto w/scope		4.43	4	17.72	1	4.43	1	4.43	27
	Glycosylated hemoglobin test		13.56	4	54.24	1	13.56	1	13.56	81
	Glucose blood test		3.27	4	13.08	1	3.27	1	3.27	20
	Assay of insulin		15.98	4	63.92	1	15.98	1	15.98	96
	Glucose tolerance test		17.99	4	71.96	1	17.99	1	17.99	108
	Assay thyroid stimulating hormone		23.47	4	93.88	1	23.47	1	23.47	141
	Complete blood cell count, automated		9.04	4	36.16	1	9.04	1	9.04	54
	Esophagram		74.66	1	74.66	1	74.66	1	74.66	224
Total		**11,472**			**1,760.64**		**505.91**		**386.91**	**14,125**

Note: Cost amounts are all in 2007 dollars.

[a] The number was derived from the 2004 value through a conversion using the Consumer Price Index developed by the U.S. Bureau of Labor Statistics.

Cost of Nonoperative Approaches

Nonoperative approaches to pediatric obesity management include dietary therapies, physical exercise, psychological and family support, residential treatment, behavioral interventions, and pharmacotherapy. These nonoperative approaches are usually combined into a comprehensive weight management program because evidence supports that the combination therapy is more successful than any single intervention.(87)

According to a survey by Marketdata (a market research organization), hundreds of weight loss programs existed in the United States in 2004.(88) Findings from the same survey indicate that a typical customized, 6-month weight loss program would cost $802 on average. Such programs are typically led by a well-trained dietitian and based in either hospitals or health clubs. For a less medically-oriented program led by a nutritionist holding a bachelor's degree, the average cost would be $643. The weight loss programs surveyed by Marketdata might enroll both adult and pediatric patients. Our literature search did not identify any cost information regarding a weight loss program specifically designed for pediatric patients with obesity/morbid obesity.

Our searches found only one study containing information on pediatric pharmacotherapy charges. Encinosa and colleagues analyzed the 2002 Medstat data for pharmacotherapy costs and found that, of the 4 million patients who had prescription drug coverage, 21,931 used medications for weight loss.(89) These patients spent $304 per year on average on weight loss medications in 2002 (26 percent was paid out of pocket and 74 percent covered by insurers). Average annual spending for weight loss medications was found to increase with age, from $192 per person for ages 8-17 to $361 for ages 55-64.

Key Question 5: Do the effectiveness, safety and cost of bariatric surgery for patients a-d (as above) vary based on patients characteristics, including:

a. Chronological age
b. Physiologic/skeletal age
c. Pre-surgical BMI
d. Pre-surgical BMI categories (35-40, 40-50, 50+ kg/m^2)
e. Sex
f. Race
g. Co-morbid conditions (e.g., Pickwickian syndrome)
h. Other factors (e.g., psychosocial or socioeconomic factors)

ECRI Institute evidence assessments:

- **The evidence is insufficient to permit any conclusions for this question**

Five studies met the inclusion criteria for this Key Question. Of the eight patient characteristics (a) through (h), the studies addressed four: chronological age (a), pre-surgical BMI (c), pre-surgical BMI category (d), and sex (e). The quality assessments appear in Appendix E, and the data appear in Table 16 below. The patient-level data for each of these four patient characteristics are plotted against individual BMI units lost. These data appear in Appendix E.

Among the five studies, there were two studies of LAGB (one moderate quality and one low quality for this Key Question). Therefore, the evidence base was of low quality overall. With only two studies, the evidence was insufficient to permit conclusions for LAGB. For the other procedures, there was only one study for this Key Question, and due to the lack of replication, we did not draw conclusions.

Table 16. Data for Key Question 5 (Patient Characteristics to Predict Outcomes)

Study	N	Correlation between patient characteristic and BMI units lost[a]			
		Age	Pre-surgical BMI	Pre-surgical BMI category	Sex
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)					
Fielding (2005)[b](71-73)	17	+0.08 (-0.42 to 0.54)	+0.66 (0.26 to 0.87)	+0.61 (0.18 to 0.84)	-0.20 (-0.62 to 0.31)
Abu-Abeid (2003)(75)	11	NR	+0.65 (0.08 to 0.90)	+0.70 (0.17 to 0.92)	NR
Studies of Roux-en-Y Gastric Bypass (RYGB)					
Strauss (2001)(36)	9	-0.51 (-0.88 to 0.24)	+0.31 (-0.45 to 0.81)	+0.04 (-0.64 to 0.69)	-0.37 (-0.83 to 0.39)
Studies of Vertical Banded Gastroplasty (VBG)					
Greenstein (1995)(81)	14	NR	+0.49 (-0.05 to 0.81)	+0.49 (-0.05 to 0.81)	-0.54 (-0.83 to -0.01)
Studies of Combined VBG-RYGB					
Capella (2003)(83)	15[c]	-0.12 (-0.63 to 0.46)	+0.50 (-0.02 to 0.81)	+0.49 (-0.03 to 0.80)	NR

a Each cell shows the patient-level Pearson r correlation (with 95% confidence interval) between a patient characteristic and the number of BMI units lost. For age, a positive correlation (+) means that older patients lost more BMI units. For the two BMI characteristics, a positive correlation means that patients with higher pre-surgical BMIs lost more BMI units than those with lower pre-surgical BMIs. The six categories of pre-surgical BMI were <40, 40-44.99, 45-49.99, 50-54.99, 55-59.99, and 60+ kg/m^2. For sex, a positive correlation means that boys lost more BMI units than girls. Figures in Appendix E show the individual patient data for all of the studies above.

b Individual patient data reported in a secondary publication(72)

c In the Capella study, the correlations with pre-surgical BMI and pre-surgical BMI category are based on 15 patients, and the age correlation is based on 13 patients

NR – Not reported

Note: Key Question 5 was addressed by studies reporting individual patient data or studies that reported the necessary correlation between a patient characteristics and an outcome. A secondary publication(69) of the Silberhumer study reported individual patient data, but 1+ year weight data was only reported for only three of eight patients. Horgan reported individual patient data, but only reported 1+ year weight data for only two of four patients.

Discussion

General considerations

Researchers have raised several special considerations about the appropriateness of bariatric surgery in a pediatric population.(35) These include informed consent, interference with physical growth/maturation, and compliance with post-surgical diets.

Regarding informed consent, Inge et al.(2004)(90) stated that one important ethical consideration is whether the pediatric patient has "decisional capacity". Patients without such capacity should not be treated surgically. Even with good decisional capacity when surgery is elected, some pediatric bariatric patients may later regret the decision to undergo surgery. If so, bariatric procedures that are more easily reversed (such as LAGB) may receive greater consideration in the pediatric population.

Another concern is the potential for bariatric surgery to interfere with physical growth and/or sexual maturation. Therefore, these additional outcomes should be considered in pediatric patients who receive bariatric surgery. In Key Question 3, we examined the published evidence for these outcomes. Only one study formally evaluated the growth of patients in post-operative followups.(37) The authors stated that "there was no evidence of growth retardation after surgery," but they also stated that "the question as to whether these adolescents achieved their expected growth could not be extracted from data available."(37) Two additional studies documented patients' pre-surgical height, but did not report height data after surgery.(82,83) Thus, the available evidence does not clarify whether bariatric surgery impairs the growth and development of pediatric patients.

Another consideration is compliance with post-surgical dietary regimens, dietary supplements, and exercise recommendations. Pediatric patients may have lower levels of compliance than adults. One study included in our review reported that only 13% of pediatric patients continued taking nutritional supplements as instructed.(37) No other included studies examined the issue. To adequately address concerns about low compliance, additional evidence is needed from future studies.

Previous Systematic Reviews

The United Kingdom National Institute for Health and Clinical Excellence (NICE) published a systematic review in 2006 on obesity in children and adolescents.(44) The review contained 16 evidence statements specific to bariatric surgery in the pediatric population, and these statements correspond well to the conclusions in our report. We summarize their statements in the context of the five Key Questions in this report. For weight loss (our Key Question 1), the NICE report concluded than an "approximate change in BMI of -20 kg/m^2 (after approximately two years) can occur in obese adolescents who underwent bariatric surgery."(44) For comorbidities and quality of life (our Key Question 2), it stated that "evidence suggests that bariatric surgery can have an impact on psychosocial adjustment of severely obese adolescents", and that "some evidence suggests that bariatric surgery can reduce significant comorbidities in severely obese adolescents."(44) For our Key Question 3 on harms, the NICE report contained four evidence statements concerning harms that may occur, including micronutrient deficiencies, revisional

surgery, and band slippage or port infection/leakage after LAGB. No evidence statements were provided about costs (our Key Question 4) or the correspondence between patient characteristics and outcomes (our Key Question 5).

The Belgian Health Care Knowledge Center reported a systematic review in 2006 that included an assessment of the evidence on bariatric surgery in patients under age 18. Based on six studies, authors concluded that "long-term efficacy and safety of bariatric surgery in patients under 18 remain to be properly documented and demonstrated" and that "this procedure should be strictly limited to few specialized centres of excellence."(91)

A systematic review by the Institute for Clinical Systems Improvement in 2005 addressed bariatric surgery in children and adolescents.(92) After describing three studies, the review concluded that "in the short term, bariatric surgery appears to lead to significant weight loss with resolution of comorbidities." "Based on small case series, bariatric surgical complications in adolescents (age 11 years or greater) are no higher than in adults, although the impact of bariatric surgery on growth, development, metabolic homeostasis, and nutritional balance is unknown."(92)

A 2004 systematic review by the Southern California-RAND Evidence-Based Practice Center specifically examined data on bariatric surgery for adolescents.(93) They discussed eight case series, and concluded that "these reports document benefits in terms of weight loss and resolution of complications as well as harms in terms of surgical complications."(93)

Another 2004 systematic review, performed by the Health Technology Assessment Unit in Malaysia, included four studies of bariatric surgery in patients aged 0-18.(94) Based on four studies, authors stated that "surgery is recommended for treatment of morbidly obese children."(94)

Ongoing Clinical Trials

Our searches of clinicaltrials.gov located three ongoing studies of bariatric surgery in pediatric patients, all of which were recruiting patients as of 4/13/07:

- One study (clinicaltrials.gov identifier NCT00289705) at Göteborg University in Sweden started in February of 2006 that involves the use of laparoscopic Roux-en-Y gastric bypass with an expected enrollment of 80 patients aged 13-17.
- Another study (clinicaltrials.gov identifier NCT00447590) by the Allergan Medical Corporation (Irvine, CA) is planned to enroll 150 obese patients aged 14-17 who will undergo LAGB with the LAP-BAND® (start date not included in the trial record).
- A third study (clinicaltrials.gov identifier NCT00360373), sponsored by the National Institute of Diabetes and Digestive Kidney Disease (NIDDK) and being conducted at the Cincinnati Children's Hospital Medical Center, started in August of 2005. The investigators plan to perform gastric bypass on 50 patients with BMI >40 in two groups (aged 15-21 or aged 30-45).

Clinical Practice Guidelines and Position Statements

This section reviews nine guidelines and position statements that addressed bariatric surgery for morbidly obese pediatric patients.

The Institute for Clinical Systems Improvement (ICSI) published a Health Care Guideline in 2006 pertaining to the prevention and management of obesity in mature adolescents and adults.(95) They defined "mature adolescents" as those who have reached Tanner stage 5 of sexual maturity (of five stages total). For this population as well as adults, the authors of the guideline concluded that "Bariatric surgery is indicated in carefully selected patients: a) with a BMI greater than or equal to 40 kg/m^2, or b) with a BMI of 35-39.9 kg/m^2 and who are at a very high absolute risk for increased morbidity or premature mortality. Patients are to be motivated, well-informed in disease management, psychologically stable, and accepting of operative risks."(95)

In a 2005 guideline, the American Heart Association (AHA) mentioned surgical treatment as one option in the treatment of overweight in children and adolescents. Authors recommended more stringent BMI indications for pediatric patients than for adults: a minimum BMI of 50 kg/m^2 or a BMI of at least 40 kg/m^2 in the presence of serious comorbidities. The guideline stated that "weight loss goals and reduction of morbidity are often achieved with gastric bypass surgery. The rates of short-term mortality appear to be low, but significant complications can occur".(39) The guideline further recommended that "surgical therapy should be reserved for full-grown adolescents with the severest obesity-related morbidity, offered only by experienced multidisciplinary teams, and presented to families with appropriate informed consent procedures."(39)

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition published a 2005 guideline on overweight children and adolescents.(96) Bariatric surgery was listed in a set of "intensive therapies for severely obese children". The guideline stated that "until more data are available, gastric bypass surgery should be considered only for well-informed and motivated adolescents who meet the following criteria: severe obesity (BMI ≥40 kg/m^2), failure of ≥6 months of organized attempts at weight loss, near-complete skeletal maturity and significant comorbidities that would be responsive to sustained weight loss."(96)

Inge et al.(2004)(90) published bariatric surgery recommendations for adolescents who are severely overweight. Like the AHA, the publication recommended that for this patient population, the BMI criteria should be more stringent than those for adults (minimum BMI of 50 kg/m^2 or a BMI of at least 40 kg/m^2 in the presence of serious comorbidities). Other indications for adolescent bariatric surgery included the attainment of physical maturity, demonstrated decisional capacity, a supportive family environment, and other criteria that are also applied to adults, such as the documented failure of previous nonsurgical attempts at weight loss.

The 2004 Consensus Conference Statement of the American Society for Bariatric Surgery states that "Bariatric surgery, performed only by experienced centers, should be considered in morbidly obese adolescents "(97) The statement also noted that since the 1991 NIH Consensus Conference on bariatric surgery, there has been "increased experience with bariatric surgery in adolescent and elderly populations."(97) Further, the statement notes that "BMI guidelines for adolescents should be identical to those advocated for adults,"(97) and it includes recommendations such as

"physiologic maturity should be complete", "adolescents should indicate their desire for the operation and should have sufficient cognitive and psychologic development to participate in decision-making", and "adolescents should first undergo a trial of dietary and behavior modification for at least 6 months."(97)

The 2004 Singapore Ministry of Health clinical practice guidelines for obesity stated that "Bariatric surgery cannot be recommended for most adolescents, but only for those at the highest risk of mortality from obesity, and with both patient and parental understanding of the consequences of surgery."(98)

In 2004, the Betsy Lehman Center for Patient Safety and Medical Error Reduction (Boston, MA) convened an Expert Panel on Weight Loss Surgery.(99) The report recommended more stringent BMI criteria for adolescents than for adults (the same BMI criteria recommended by the Inge document discussed above).(90) About the effectiveness of bariatric surgery, the panel concluded that "the limited data available indicate that Roux-en-Y Gastric Bypass (RYGB) and laparoscopic adjustable gastric banding (LAGB) are generally safe and produce durable weight loss when used in adolescents."(99)

The University of Texas at Austin published a 2004 guideline on the evaluation and treatment of obesity in children and adolescents.(100) One of the statements on patient management stated "Referral to specialty weight reduction clinics including consideration of medication and/or bariatric surgery (needed in less than 1% of children and adolescents identified as obese)."(100)

In 2003, the Australian National Health and Medical Research Council (NHMRC) published clinical practice guidelines for the management of overweight and obesity in children and adolescents.(101) With respect to bariatric surgery, the guideline concluded that "There is limited evidence that gastric bypass or gastric restrictive surgery in obese adolescents induces a weight loss comparable to that shown in adult studies. There are, however, no established criteria for determining which subjects would benefit from such a procedure."(101)

Conclusions

In this section, we first summarize the five clinical questions and the conclusions we drew based on the evidence (for more detailed descriptions of the evidence, please consult the *Results* section starting on page 36). Then, we provide general comments on the overall picture of the evidence pertaining to bariatric surgery for morbidly obese pediatric patients.

1. Does pediatric bariatric surgery lead to sustained and clinically significant weight loss compared to non-operative approaches?
    a. In patients aged 21 or less
    b. Specifically in patients aged 18-21
    c. Specifically in patients aged 13-17
    d. Specifically in patients aged 12 or less

ECRI Institute evidence assessments:

- Laparoscopic Adjustable Gastric Banding (LAGB) for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches. Strength of evidence: Moderate.

- Roux-en-Y Gastric Bypass (RYGB) for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches. Strength of evidence: Moderate to Weak.

- The evidence is insufficient to permit quantitative estimates of the precise amount of weight loss after any bariatric surgical procedure for pediatric patients.

- The evidence is insufficient to permit any conclusions about weight loss after other bariatric surgical procedures for pediatric patients.

- The evidence is insufficient to permit any conclusions about weight loss in specific age subgroups (18-21, 13-17, 12 or less) within the pediatric population.

2. Does bariatric surgery for patients a-d (as above) improve co-morbid conditions linked to obesity (e.g., diabetes, hypertension, obstructive sleep apnea, musculoskeletal disorders), quality of life, or survival, as compared to non-operative approaches?

ECRI Institute evidence assessments:

- Laparoscopic Adjustable Gastric Banding (LAGB) for morbidly obese patients aged 21 or less does resolve co-morbid conditions linked to obesity (hypertension, dyslipidemia, asthma) compared to non-operative approaches. Strength of evidence: Weak.

- Roux-en-Y Gastric Bypass for morbidly obese patients aged 21 or less does resolve co-morbid conditions linked to obesity (hypertension, sleep apnea) compared to non-operative approaches. Strength of evidence: Weak.

- The evidence is insufficient to permit quantitative estimates of the likelihood of comorbidity resolution, quality of life, or survival after any bariatric surgical procedure for pediatric patients.

- The evidence is insufficient to permit any conclusions about comorbidity resolution after other bariatric surgical procedures for pediatric patients.

- The evidence is insufficient to permit any conclusions about comorbidity resolution in specific age subgroups (18-21, 13-17, 12 or less) within the pediatric population.

3. What are the relative safety profiles of bariatric surgery and non-operative approaches for patients a-d (as above)?

ECRI Institute evidence assessments:

- The strength of the evidence for adverse events was Moderate.

- No perioperative mortality was reported across included studies.

- One late death was reported in a RYGB study; no late death was reported in other included studies.

- The overall reoperation rate for the LAGB cases was 9.39%; such reoperation rate was not available for the RYGB cases.

- The most frequently reported postoperative complication for LAGB was band slippage.

- The most frequently reported postoperative complication for RYGB was problems related to protein-calorie malnutrition and micronutrient deficiency.

- Potentially severe adverse events after RYGB included pulmonary embolism, severe malnutrition, immediate postoperative bleeding, gastrointestinal obstruction, and staple line leak.

- The evidence is insufficient to permit any conclusions about whether bariatric surgery would have any negative impacts on growth and development of pediatric patients.

- The evidence is insufficient to permit any conclusions about potential harms in specific age subgroups (18-21, 13-17, 12 or less) within the pediatric population.

- Systematic reviews on pediatric obesity management did not provide sufficient data for the development of a safety profile of nonoperative approaches.

4. What are the relative cost profiles of bariatric surgery and non-operative approaches for patients a-d (as above)?

ECRI Institute evidence assessments:

- In 2004, the median hospital inpatient cost for pediatric bariatric surgery was $8,651; the median hospital inpatient charge was $25,021.

- No significant difference in hospital inpatient cost or charge was found between the 13-17 and the 18-21 age groups in 2004. No conclusions can be drawn regarding the cost or charge of patients aged less than 12 due to lack of data.

- We estimated that the total three-year cost of a pediatric LAGB procedure without major postoperative complications is $11,628 in 2007. This total cost contains a cost of $2,793 for postoperative care in the first three years after surgery.

- We estimated that the total three-year cost of a pediatric RYGB procedure (open approach) without major postoperative complications is $14,125 in 2007. This total cost contains a cost of $2,653 for postoperative care in the first three years after surgery.

- Data were not sufficient to permit a comparison of cost between the State of Washington and the nation.

- The evidence was not sufficient to permit the development of a comprehensive cost profile of nonoperative approaches to pediatric obesity management.

5. Do the effectiveness, safety and cost of bariatric surgery for patients a-d (as above) vary based on patients characteristics, including:
    a. Chronological age
    b. Physiologic/skeletal age
    c. Pre-surgical BMI
    d. Pre-surgical BMI categories (35-40, 40-50, 50+)
    e. Sex
    f. Race
    g. Co-morbid conditions (e.g., Pickwickian syndrome)
    h. Other factors (e.g., psychosocial or socioeconomic factors)

ECRI Institute evidence assessments:

- The evidence is insufficient to permit any conclusions for this question

General Comments

The primary benefits of LAGB and RYGB for pediatric patients with morbid obesity are the substantial weight loss (Key Question 1) and the resolution of medical conditions associated with obesity (Key Question 2). Sufficient evidence has accumulated to demonstrate these benefits in pediatric populations. However, direct evidence on enhanced quality of life and extended long-term survival is too sparse (or simply unavailable) to support conclusions. Also, current evidence does not permit conclusions about whether certain patient characteristics (e.g., age, sex, pre-surgical BMI) are predictive of surgical outcomes (Key Question 5).

The potential benefits of bariatric surgery must be weighed against the adverse events (Key Question 3). For LAGB, the primary concern is the need for reoperation to correct problems

associated with the band and port. Reasons for reoperation include band slippage, intragastric migration, and port/tubing problems. For RYGB, there is a different profile of adverse events, varying from mild events (e.g., slight malnutrition, correctable by supplements) to severe events (e.g., pulmonary embolism, severe malnutrition, immediate postoperative bleeding, digestive obstruction, staple line leak). Precisely how often these events occur in pediatric patients is unknowable, due to the sparseness of the evidence.

The costs associated with bariatric surgery (Key Question 4) include not only the hospital inpatient costs of the procedure, but also the postoperative management costs for these patients. Unfortunately, no published data exists on bariatric costs in pediatric patients. Therefore, we conducted our own analyses of publicly available data to estimate hospital inpatient costs, costs of professional services, and postoperative care costs. Based on these analyses, we estimated the overall three-year cost of LAGB without major complications at $11,628 (in 2007 dollars). The corresponding cost for RYGB using an open approach was $14,125.

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Appendix A. Literature Search Methods

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date limits	Platform/provider
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	2003 through June 4, 2007	OVID
The Cochrane Central Register of Controlled Trials (CENTRAL)	2003 through 2007 Issue 2	http://www.thecochranelibrary.com
The Cochrane Database of Methodology Reviews (Methodology Reviews)	2003 through 2007 Issue 2	http://www.thecochranelibrary.com
The Cochrane Database of Systematic Reviews (Cochrane Reviews)	2003 through 2007 Issue 2	http://www.thecochranelibrary.com
Database of Abstracts of Reviews of Effects (DARE)	2003 through 2007 Issue 2	http://www.thecochranelibrary.com
Embase (Excerpta Medica)	2003 through June 4, 2007	OVID
Health Technology Assessment Database (HTA)	2003 through 2007 Issue 2	http://www.thecochranelibrary.com
Healthcare Standards	1975 through April 10, 2007	ECRI
International Health Technology Assessment (IHTA)	2003 through April 10, 2007	ECRI
MEDLINE	2003 through June 4, 2007	OVID
metaRegister of Controlled Trials (mRCT)	Searched April 13, 2007	http://www.controlled-trials.com/mrct/
PsycINFO	2003 through June 4, 2007	OVID
PubMed (PREMEDLINE)	Premedline[sb] Searched April 16, 2007	http://www.pubmed.gov
U.K. National Health Service Economic Evaluation Database (NHS EED)	2003 through 2007 Issue 2	http://www.thecochranelibrary.com
U.S. National Guideline Clearinghouse™ (NGC™)	2003 through April 10, 2007	http://www.ngc.gov

Detailed Search Strategies

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across Embase, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), Emtree, PsycINFO and Keywords

Conventions:

OVID

$ = truncation character (wildcard)

exp = "explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)

.de. = limit controlled vocabulary heading

.fs. = floating subheading

.hw. = limit to heading word

.md. = type of methodology (PsycINFO)

.mp. = combined search fields (default if no fields are specified)

.pt. = publication Type

.ti. = limit to title

.tw. = limit to title and abstract fields

PubMed

[mh] = MeSH heading

[majr] = MeSH heading designated as major topic

[pt] = Publication Type

[sb] = Subset of PubMed database (PreMedline, Systematic, OldMedline)

[sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)

[tiab] = keyword in title or abstract

[tw] = Text word

CINAHL/Embase/Medline/PsycINFO
English language, human
Date range 2003 - 2007

Set Number	Concept	Search statement
1	Bypass surgery	Exp bariatric surgery/ or roux y anastomosis.de. or anastomosis, roux-en-y.de. or stomach bypass.de. or biliopancreatic bypass.de. or biliopancreatic diversion.de. or gastric bypass or intestinal bypass or fobi pouch or silastic pouch or bariatrics.de.
2	Gastric banding	(silastic or vertical or silicone ring or horizontal or collis) and (band$ or gastroplasty)
3	Specific products	Lap band or lapband or lap-band
4	Surgery	Obesity morbid/su or morbid obesity/su
5	Specific trials	“assess cost-effectiveness in obesity project”
6	Combine sets	or/1-5
7	General Limits	6 and 2003-2007 publication date, human, and English language
8	Limit by population	7 and (exp child/ or adolescent.de. or child$ or pediatr$ or paediatr$ or juvenile$ or adolescen$ or teen$ or youth$) Note: We may consider using the term age factors as another means of addressing this subject.
9	Limit by study type	8 and ((Randomized controlled trials or random allocation or double-blind method or single-blind method or placebos or cross-over studies or crossover procedure or double blind procedure or single blind procedure or placebo or latin square design or crossover design or double-blind studies or single-blind studies or triple-blind studies or random assignment or exp controlled study/ or exp clinical trial/ or exp comparative study/ or cohort analysis or follow-up studies.de. or intermethod comparison or parallel design or control group or prospective study or retrospective study or case control study or major clinical study).de. or random$.hw. or random$.ti. or placebo$ or ((singl$ or doubl$ or tripl$ or trebl$) and (dummy or blind or sham)) or latin square or ISRTCN)
10	Economic analyses	8 and (Exp economic evaluation/ or exp costs and cost analysis/ or ec.fs. or cost$.sh. or (econom$ or cost$).ti.)
11	Combine sets	or/9-10
12	Limit by publication type	11 not ((letter or editorial or news or comment or case reports or review or note or conference paper).de. or (letter or editorial or news or comment or case reports or review).pt.)
13	Eliminate overlap	Remove duplicates from 12

PubMed
(PREMEDLINE/Publisher Sub-files)
English language, human

Set Number	Concept	Search statement
1	Obesity	Bariatric*[ti] OR obes*[ti]
2	Surgery	#1 AND surg*
3	Specific procedures	"gastric bypass" OR (band* AND (silastic OR vertical OR "silicone ring" OR horizontal OR collis))
4	Combine sets	#2 OR #3
5	Limit by population	#4 AND (child* OR pediatr* OR paediatr* OR juvenile OR teen OR adolescen*)
6	Limit by sub-file	#5 AND (in process[sb] OR publisher[sb])
7	Limit by publication type	#6 NOT (letter[pt] OR editorial[pt] OR news[pt] OR comment[pt] OR case reports[pt])

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI's collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

Appendix B. Excluded Studies

Table 17. Excluded Studies

Study	Reason for exclusion
Anderson et al. (1980)(102)	Patients did not receive a bariatric surgical procedure of interest
Benotti et al. (2006)(103)	Not a pediatric population
Breaux et al. (1995)(104)	39% of surgical procedures were VBG or BPD, and the remaining 61% were RYGB, but authors did not report separate data for RYGB patients
Haby et al. (2006)(105)	Not a primary research study
Inge et al. (2004)(106)	Abstract only
Metzelder et al. (2006)(107)	Not bariatric surgery
Organ et al. (1984)(108)	Patients did not receive a bariatric surgical procedure of interest
Randolph et al. (1974)(109)	Patients did not receive a bariatric surgical procedure of interest
Silber (1986)(110)	Patients did not receive a bariatric surgical procedure of interest
Soper et al. (1975)(111)	Patients did not receive a bariatric surgical procedure of interest
Towbin et al. (2004)(112)	Only examined one adverse event; no indication of the frequency of this event in the population
Vishne et al. (2004)(113)	Not a pediatric population

Appendix C. Quality of Literature and Evidence Strength

Study Quality Assessment

The prior unsuccessful attempts at non-surgical weight loss in patients who choose to undergo bariatric surgery mean that it is a reasonable assumption that patients would not have lost weight without surgery. Therefore, we did not require that studies enroll a control group of patients who received non-surgical treatment.

To rate the quality of case series of bariatric surgery, we considered four factors: whether the study was prospective, whether patients had been enrolled consecutively within a time period, and whether the data included at least 85% of those enrolled, and whether the study was not funded by a financially interested party. If a study did not report sufficient information for us to determine whether a factor was met, we assumed that it was not met. If a study met all four factors, it was considered High quality. If a study met two or three factors, it was considered Moderate quality. If it met only one factor, it was considered Low quality. If it met none of the factors, it was considered Very Low quality and was excluded from the evidence base.

Strength of Evidence System

In evaluating the stability and strength of a body of literature, we used the ECRI Institute strength-of-evidence system.(53) This system employs decision points that collectively yield an overall category that describes the strength of the evidence for a quantitative estimate and qualitative conclusion as strong, moderate, weak, or unacceptably weak. The qualitative conclusion addresses the question, “Does it work?” The quantitative estimate addresses the question, “How well does it work?” This distinction allows an evidence base to be considered weak in terms of the quantitative estimate of effect (e.g., if estimates vary widely among studies) but strong or moderate with respect to the qualitative conclusion (e.g., if all studies nevertheless demonstrate the same direction of effect).

The system addresses five general aspects of the evidence: quality, quantity, consistency, robustness, and magnitude of effect. Quality refers to the degree of potential bias in the design or conduct of studies. Quantity refers to the number of studies and the number of enrolled patients. Consistency addresses the degree of agreement among the results of available studies. Robustness involves the constancy of conclusions in the face of minor hypothetical alterations in the data. Magnitude of effect concerns the quantitative amount of benefit (or harm) that patients experience after treatment, and it is only considered in the qualitative section of the system.

The output of the system is two ratings: a stability rating (which pertains to a quantitative conclusion) and a strength rating (which pertains to a qualitative conclusion). Interpretations of the two types of ratings appear in the table below.

Table 18. Interpretation of Different Categories of Strength of Evidence Supporting Conclusion

Strength of Evidence	Interpretation
Qualitative Conclusion (Direction of Effect)	
Strong Evidence	Evidence supporting the qualitative conclusion is convincing. It is highly unlikely that new evidence will lead to a change in this conclusion.
Moderate Evidence	Evidence supporting the qualitative conclusion is somewhat convincing. There is a small chance that new evidence will overturn or strengthen our conclusion. ECRI recommends regular monitoring of the relevant literature at this time.
Weak Evidence	Although some evidence exists to support the qualitative conclusion, this evidence is tentative and perishable. There is a reasonable chance that new evidence will overturn or strengthen our conclusions. ECRI recommends frequent monitoring of the relevant literature at this time.
Inconclusive	Although some evidence exists, this evidence is not of sufficient strength to warrant drawing an evidence-based conclusion from it. ECRI recommends frequent monitoring of the relevant literature at this time.
Quantitative Conclusion (Magnitude of Effect)	
High Stability	The estimate of diagnostic test performance included in the conclusion is stable. It is highly unlikely that the magnitude of this estimate will change substantially as a result of the publication of new evidence.
Moderate Stability	The estimate of diagnostic test performance included in the conclusion is somewhat stable. There is a small chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI recommends regular monitoring of the relevant literature at this time.
Low Stability	The estimate of diagnostic test performance included in the conclusion is likely to be unstable. There is a reasonable chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI recommends frequent monitoring of the relevant literature at this time.
Unstable	Estimates of the diagnostic test performance are too unstable to allow a quantitative conclusion to be drawn at this time. ECRI recommends frequent monitoring of the relevant literature.

To arrive at these strength and stability ratings, we applied the ECRI Strength and Stability of Evidence System. The methods we used to resolve these decision points appear below.

Decision Point 1: Determining Quality of Individual Studies

For this decision point, we excluded any study that did not meet any of the three quality factors (see previous section). The remaining studies constituted the evidence base for the rest of the system.

Decision Point 2: Determine Quality of Evidence Base

We classified the overall quality of the evidence base by taking the median quality category of the individual studies. We used the median because it is the appropriate measure of central tendency to represent the "typical" quality category, and is less sensitive to outliers than the mean. Depending on the overall quality categories for each outcome, we then followed the high, moderate, or low quality branch of the system. If the median category fell between two categories, we proceeded with the lower quality category.

The quality of the evidence base sets an upper limit on judgments of the strength and stability of the evidence. For example, the strength of evidence can be weak, moderate, or strong if the evidence base is of high quality, but the strength can never be strong if the evidence base is of moderate or low quality. Because the quality was determined separately for each outcome, a study that scored as moderate quality for one outcome might score as low quality for another outcome.

Decision Point 3: Is Quantitative Analysis Possible?

The answer to Decision Point 3 depends upon the adequacy of reporting in available studies as well as the number of available studies. In order to conduct a quantitative analysis of a given outcome, the data for that outcome must be reported in at least three studies in a manner that allows the data to be pooled in a meta-analysis. If so, we proceeded to Decision Point 4. If less than three studies are available, no quantitative analysis is usually possible regardless of reporting. Another situation that does not allow a quantitative analysis is when three or more studies are available, but fewer than 75% of them permit determination of the effect size and its dispersion, either by direct reporting from the trial or calculations based on reported information. If no quantitative analysis was possible, then we moved directly to Decision Point 8 to determine whether the data permitted a qualitative conclusion.

Decision Point 4: Are Data Quantitatively Consistent (Homogeneous)?

This decision point was used only if the answer to Decision Point 3 was Yes. Consistency refers to the extent to which the results of studies in an evidence base agree with each other. The more consistent the evidence, the more precise a summary estimate of treatment effect derived from the evidence base. Quantitative consistency refers to consistency tested in a meta-analysis using Higgins and Thompson's I^2 statistic.(114) We considered the evidence base to be quantitatively consistent when $I^2 < 50\%$.(114)

If the evidence base was quantitatively consistent (i.e., homogeneous), we combined the results to yield a meta-analytic summary statistic. We then tested the robustness of this summary estimate in Decision Point 5. If it was not homogeneous, then Decision Point 5 was not applicable, and we proceeded to Decision Point 6.

Decision Point 5: Are Findings Stable (Quantitatively Robust)?

To be considered quantitatively robust, the summary estimate must have met all five of the following conditions:

1) Sufficiently narrow confidence interval around the summary effect size. This is defined as an interval that is not bigger than twice the level of clinical significance (clinical significance is defined below in the section labeled "Informative").
2) After removal of one study at a time, the summary effect size never strays further than 1 unit of clinical significance away from the all-study effect size.
3) Cumulative robustness test by year, using the same criterion as for removal of one study at a time.
4) After the use of a before-after correlation at the lower bound of the 95% confidence for an imputed correlation, the summary effect size never strays further than 1 unit of clinical significance away from the original effect size.
5) After the use of a before-after correlation at the upper bound of the 95% confidence for an imputed correlation, the summary effect size never strays further than 1 unit of clinical significance away from the original effect size.

If the summary estimate did not meet all five of these conditions, it was deemed not quantitatively robust.

Decision Points 6 and 7: Exploration of Heterogeneity

Decision Points 6 and 7 are relevant only when one has, during a quantitative analysis, found that the findings of the studies that comprise an evidence base are determined to be heterogeneous (see Decision Point 4).

Decision Point 6: Does Meta-regression Explain Heterogeneity?

If we observed heterogeneity, we next attempted (if there were at least 5 studies) to explain the heterogeneity using meta-regression. If there were fewer than 5 studies in this situation, we did not arrive at a quantitative estimate. A priori, we planned to use the following factors as predictor variables in meta-regression:

- Whether the study was prospective (Yes, No, or not reported)
- Whether the study enrolled consecutive patients in a time period
- The actual percentage of patients with reported data to the timepoint of interest
- The overall quality category (high, moderate, low)
- For weight data on longest followup, the length of followup.
- For LAGB, the proportion of patients who received LAP-BAND® (as opposed to SAGB).
- For RYGB, the length of the roux limb
- For VBG, the size of the gastric pouch

We decided that a meta-regression could be considered to have explained the heterogeneity if the covariate was statistically significant, and if the resulting I^2 was less than 50%.

Decision Point 7: Is Meta-regression Model Stable?

The purpose of Decision Point 7 is to test the stability of any quantitative findings that may emanate from meta-regression analysis. We used the same robustness tests as in Decision Point #5.

Decision Point 8: Are Qualitative Findings Robust?

To be considered qualitatively robust, the conclusion must have met all six of the following conditions:

1) After removal of one study at a time, the qualitative conclusion remains the same.
2) Cumulative robustness test by year, with the qualitative conclusion remains the same.
3) Under the assumption that patients would lose 0.5 BMI units at one year if they had not had surgery, the qualitative conclusion remains the same. This number is based on a study by Chanoine(115) that found that adolescents who received non-surgical treatments had a BMI reduction of 0.5 after one year of treatment.
4) Under the assumption that patients would lose 1.3 BMI units at one year if they had not had surgery, the qualitative conclusion remains the same. This number is based on the result of the control group in the Lawson study.(66)
5) After the use of a before-after correlation at the lower bound of the 95% confidence for an imputed correlation (i.e., 0.36), the qualitative conclusion remains the same.
6) After the use of a before-after correlation at the upper bound of the 95% confidence for an imputed correlation (i.e., 0.76), the qualitative conclusion remains the same.

If the analysis did not meet all six of these conditions, it was deemed not qualitatively robust.

Decision Point 9: Are Data Qualitatively Consistent?

This Decision Point is used only when the evidence base for an outcome consists of two studies. For our purposes, the two studies were considered qualitatively consistent if they met either of the following two situations: 1) both studies showed a statistically significant effect in the same direction; or 2) neither study showed a statistically significant effect.

Decision Point 10: Is Magnitude of Treatment Effect Extremely Large?

When considering the strength of evidence supporting a qualitative conclusion based on only one or two studies, magnitude of effect becomes very important. The more positive the findings, the more confident one can be that new evidence will not overturn a general conclusion that the treatment is beneficial.

The system divides the magnitude of effect into two categories: large and not large. Determining the threshold above which the observed magnitude of effect can be considered to be "extremely large" cannot usually be determined *a priori*. The lead analyst presented the findings to other methodologists who independently determined whether an effect was "large" (blinded to each other's judgments). Disagreements were resolved in committee using a modified Delphi technique.

Other parts of the system

Some parts of the system are not formally called "Decision Points", and yet some decisions must be made in order to apply them. These are described next.

Informative?

When there are only a small number of patients in an evidence base, statistical tests generally do not perform well. Under such circumstances, statistics cannot determine whether a true difference exists between treatments. This means that no clear conclusion can be drawn. For this decision point, we determined whether the precision of an evidence base was sufficient to permit

a conclusion. Statistically significant results are potentially conclusive because they mean that a treatment effect may exist. Statistically non-significant results are also potentially conclusive, but only if they exclude the possibility that a clinically significant treatment effect exists.

When considering the summary effect size from a meta-analysis (or the effect size from a single study), there are three ways in which the effect can be "informative":

1) The summary effect size is statistically significantly different from 0. This would be indicated whenever the confidence interval does not overlap 0.
2) The summary effect size is not statistically significantly different from 0, but the confidence intervals are narrow enough to exclude the possibility that a *clinically significant difference* exists (see below for definitions of clinical significance).
3) The summary effect size is not statistically significantly different from 0, but the confidence intervals are narrow enough to exclude the possibility that a *substantial difference* exists. This possibility is included to address situations when even a very small effect can be considered "clinically significant" (e.g., a difference in mortality rates), but the effect may not be "substantial".

For weight loss, a clinical significant amount was defined as 7% of body weight, because patients who lose this amount of weight have been shown by other researchers to yield substantial reduction in medical comorbidities of obesity.(55,56) This is more stringent than the definition of clinically significant weight loss of 5% body weight that is used by the U.S. FDA and by the U.K. NICE.(57) In the included LAGB studies, 7% of body weight in the enrolled patients corresponds to 3.5 BMI units. In the included RYGB studies, 7% of body weight in the enrolled patients corresponds to 4 BMI units. In the included VBG studies, 7% of body weight in the enrolled patients corresponds to 3.9 BMI units.

A "substantial" difference in comorbidity resolution, adverse events, or mortality was defined as an odds ratio of 1.5 for dichotomous outcomes or a Hedges' d effect size of 0.2 for continuous data.

Sufficient Data for Meta-Regression?

We required a minimum of five studies before attempting meta-regression.

Mega-Trial?

We defined a mega-trial as any trial that reported data on 1,000 or more patients.

Meta-Analysis Possible?

For continuous outcomes, meta-analysis is possible when the pertinent studies either report effect sizes and standard errors, or there is sufficient reported information for both effect sizes and standard errors to be calculated. For dichotomous outcomes, meta-analysis is possible when the pertinent studies report the total number of patients in each group as well as the number of events in each group.

Figure 14. Entry into System

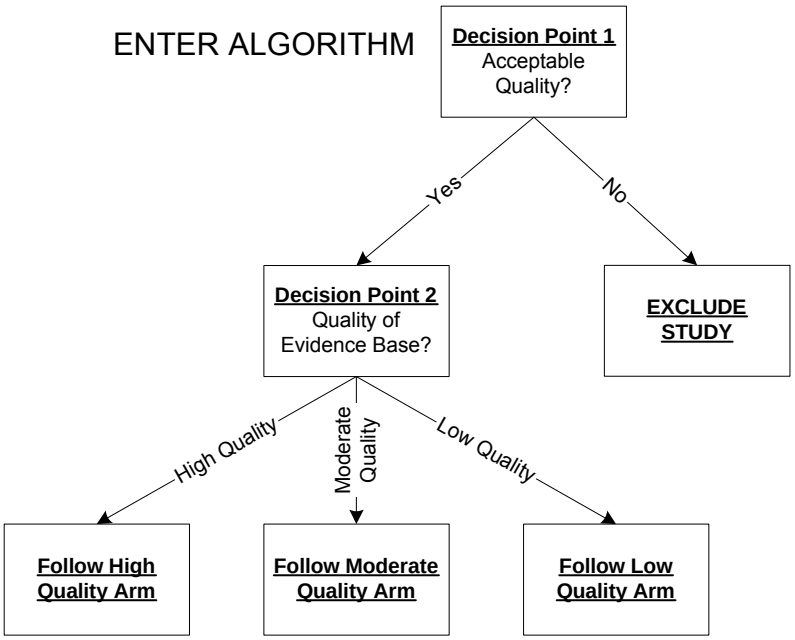


Figure 15. High-Quality Arm

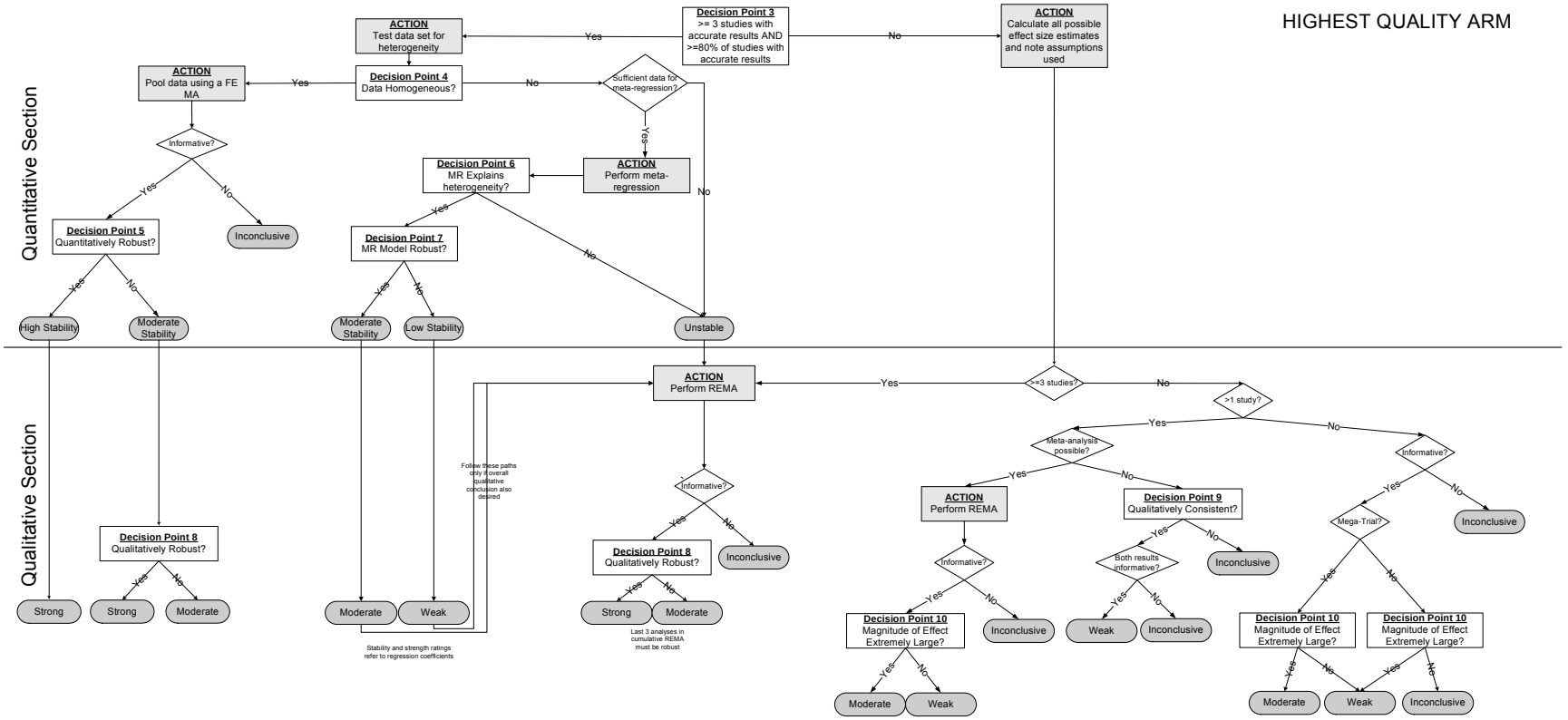


Figure 16. Moderate-Quality Arm

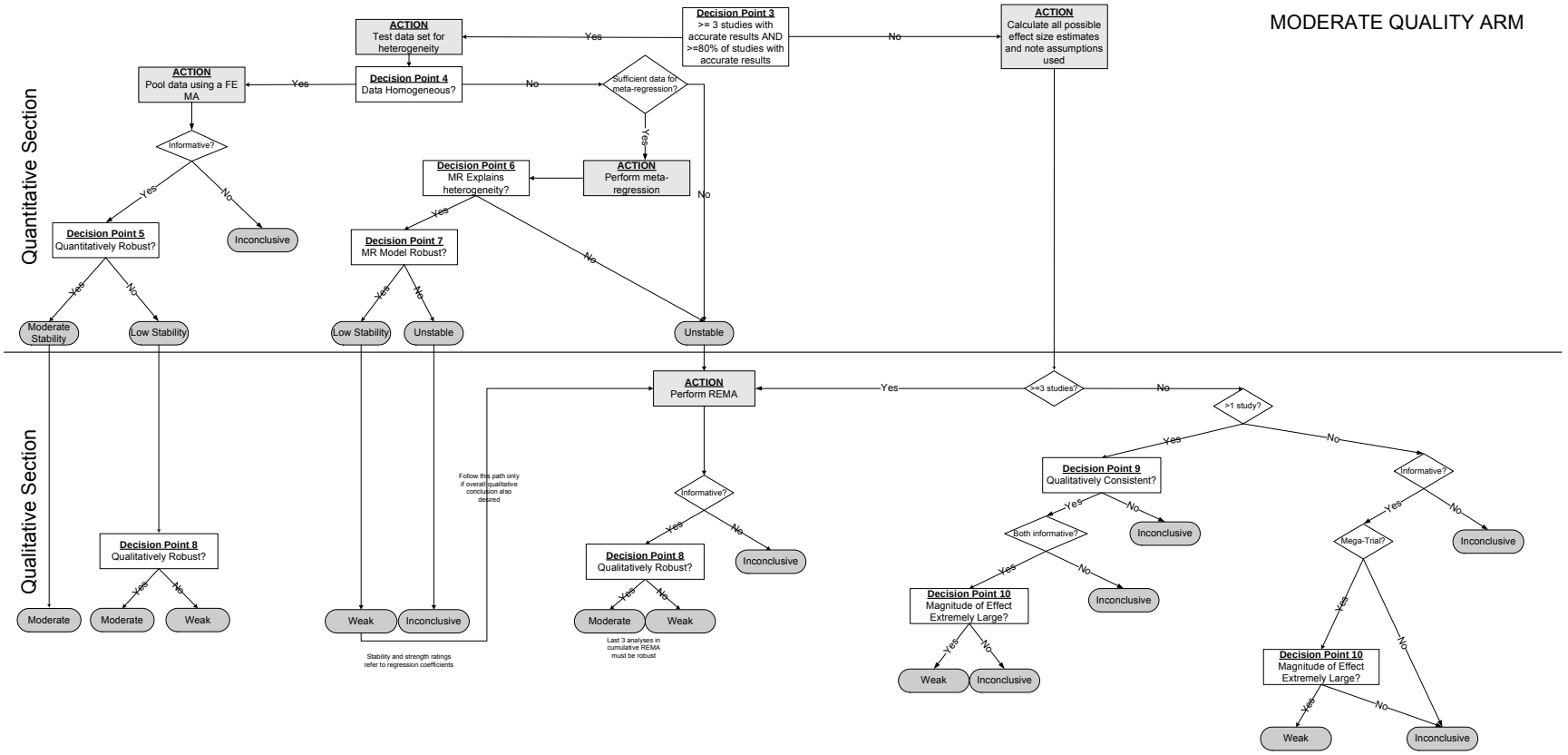
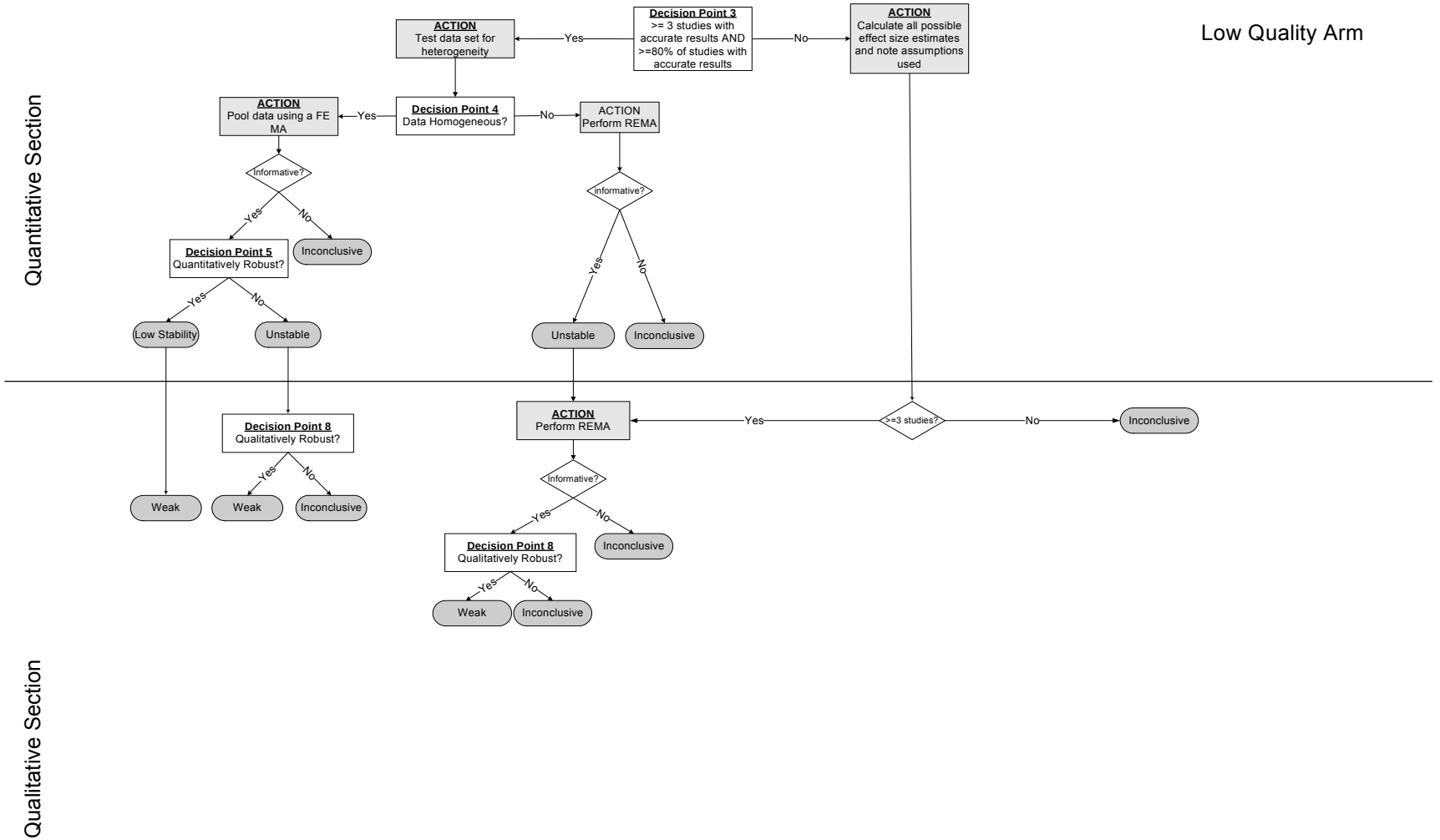


Figure 17. Low-Quality Arm



Appendix D. ICD-9-CM Codes

The following is a list of the ICD-9-CM codes that we used to select bariatric surgery cases and exclude nonbariatric surgery cases.

Diagnosis Codes:

278.0 Overweight and obesity

Excludes:

adiposogenital dystrophy (253.8)

obesity of endocrine origin NOS (259.9)

Use additional code to identify Body Mass Index (BMI) if known (V85.0-V85.54)

278.00 Obesity, unspecified

Obesity NOS

278.01 Morbid obesity

Severe obesity

278.1 Localized adiposity

Fat pad

278.8 Other hyperalimentation

1500 to 1599 Stomach and intestinal cancers

2301 to 2309 In-situ cancers

Procedure Codes:

44.31 High gastric bypass
Printen and Mason gastric bypass

44.38 Laparoscopic gastroenterostomy
Bypass: gastroduodenostomy
gastroenterostomy
gastrogastrostomy
Laparoscopic gastrojejunostomy without gastrectomy NEC
Excludes:
gastroenterostomy, open approach (44.39)

44.39 Other gastroenterostomy
Bypass:
gastroduodenostomy
gastroenterostomy
gastrogastrostomy
Gastrojejunostomy without gastrectomy NOS

44.68 Laparoscopic gastroplasty
Banding
Silastic vertical banding
Vertical banded gastroplasty (VBG)
Code also any synchronous laparoscopic gastroenterostomy (44.38)
Excludes:
insertion, laparoscopic adjustable gastric band (restrictive procedure) (44.95)
other repair of stomach, open approach (44.61-44.65, 44.69)

44.69 Other
Inversion of gastric diverticulum
Repair of stomach NOS

44.95 Laparoscopic gastric restrictive procedure
Adjustable gastric band and port insertion
Excludes:
laparoscopic gastroplasty (44.68)
other repair of stomach (44.69)

44.96 Laparoscopic revision of gastric restrictive procedure
Revision or replacement of:
adjustable gastric band
subcutaneous gastric port device

44.97 Laparoscopic removal of gastric restrictive device(s)
Removal of either or both:
adjustable gastric band
subcutaneous port device
Excludes:
nonoperative removal of gastric restrictive device(s) (97.86)
open removal of gastric restrictive device(s) (44.99)

44.98 (Laparoscopic) adjustment of size of adjustable gastric restrictive device
Infusion of saline for device tightening
Withdrawal of saline for device loosening
Code also any:
abdominal ultrasound (88.76)
abdominal wall fluoroscopy (88.09)
barium swallow (87.61)

The following is a list of the concurrent ICD-9-CM procedure codes that we used to identify the cases performed laparoscopically:**54.21 Laparoscopy (77)**
Peritoneoscopy
Excludes:
laparoscopic cholecystectomy (51.23)
that incidental to destruction of fallopian tubes (66.21-66.29)

47.01 Laparoscopic appendectomy

47.11 Laparoscopic incidental appendectomy51.23 Laparoscopic cholecystectomy (17)
That by laser

54.51 Laparoscopic lysis of peritoneal adhesions (1)

65.01 Laparoscopic oophorotomy

65.25 Other laparoscopic local excision or destruction of ovary

65.31 Laparoscopic unilateral oophorectomy

65.39 Other unilateral oophorectomy
Excludes:
that by laparoscope (65.31)

65.41 Laparoscopic unilateral salpingo-oophorectomy

65.63 Laparoscopic removal of both ovaries and tubes at same operative episode

65.64 Laparoscopic removal of remaining ovary and tube

65.81 Laparoscopic lysis of adhesions of ovary and fallopian tube

68.51 Laparoscopically assisted vaginal hysterectomy (LAVH)

Appendix E. Evidence Tables

Table 19. General Aspects of Included Studies

Study	Location	Prior non-surgical attempts at weight loss	Dates of surgery	Procedural details
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)				
Nadler (2007)(61)	New York University School of Medicine, USA	"All patients met National Institutes of Health (NIH) consensus development conference criteria for bariatric surgery" (NIH criteria include multiple prior attempts at weight loss using non-surgical methods)	9/2001 – 2/2006	Lap-Band®, placed using pars flaccida technique at 1-2 cm below the gastroesophageal junction. Band sizes were 9.75cm, 10cm, or 11cm.
Yitzhak (2006)(67)	Ben-Gurion University of the Negev, Israel	"All the patients fulfilled the NIH criteria for bariatric surgery, and had failed conservative means of weight reduction before turning to surgery"	2000 – 2006	SAGB, before 7/2002 placement was using "pars flaccida technique but through a lower tunnel which passed freely in the lesser sac". After 7/2002, "a higher pars flaccida technique with extraperitoneal dissection was used."
Silberhumer (2006)(68,69)	Medical University of Vienna, Austria	"All referred patients failed to reduce and maintain weight loss by resorting to several methods of therapeutic procedures, such as diet camps, behavioral and drug therapy. After some time, all patients gained weight again and showed severe psychological problems and social withdrawal".	1998 - 2004	Lap-Band® in 13/50 patients, and SAGB in 37/50 patients.
Angrisani (2005)(70)	Citta della Scienza, via Coroglio, Italy	One of the inclusion criteria was "failure to obtain weight loss after ≥1 year of conservative medical treatment".	1/1996 – 12/2003	Lap-Band® placement via perigastric access in 55 patients and pars flaccida in 3 patients.
Fielding (2005)(71-73)	Wesley Hospital, Australia	Used NIH criteria for bariatric surgery.	1998 – 2003	Lap-Band®. "Since 1999 we have placed the band posteriorly behind the esophagus and not the stomach, to create a smnall anterior pouch of stomach in an attempt to prevent slippage of the band into the lesser sac"
Horgan (2005)(74)	University of Illinois at Chicago, USA	All had failed medically supervised attempts at weight loss for at least 6 months.	2001 - 2003	Lap-Band®, placed using pars flaccida technique.
Abu-Abeid (2003)(75)	Tel-Aviv University, Israel	"Before referral to our center, the adolescents had been under the care of a dietician for at least 1 year and had failed to reduce weight despite a low calorie diet of about 800 Kcal/d."	Not reported	Lap-Band® placed 2cm below the gastroesophageal junction

Study	Location	Prior non-surgical attempts at weight loss	Dates of surgery	Procedural details
Studies of Roux-en-Y Gastric Bypass (RYGB)				
Collins (2007)(76,77)	University of Pittsburgh Medical Center, USA	"All patients met, at a minimum, the established criteria set by the National Institutes of Health (NIH) for candidacy for bariatric surgery"."All have attempted to lose weight by conventional means".	1999 - 6/2005	Laparoscopic RYGB via Schauer-Okramuddin technique.
Lawson (2006)(66,78-80)	Cincinnati Children's Hospital Medical Center, USA	"Failure of at least 6 months of medically supervised weight loss attempts"	5/2001 – 10/2003	Laparoscopic RYGB in 34/39, 3 open RYGB, and 2 converted to open. Roux limb lengths ranged from 75 cm (for BMI <50) to 150 cm (for BMI ≥50). Gastric pouch estimated 30-45 mL.
Barnett (2005)[a](65)	University of Minnesota School of Medicine, USA	"All patients were considered eligible for bariatric surgery according to the National Institutes of Health adult criteria"	1978 – 2001	Open RYGB
Sugerman (2003)(35)	Virginia Commonwealth University, USA	Used NIH criteria for bariatric surgery.	1981 – 1/2002	15 open RYGB with standard Roux limb length, 2 laparopscopic RYGB with standard Roux limb length, 10 long-limb RYGB, 3 distal RYGB, 2 VBG, 1 horizontal gastroplasty.
Strauss (2001)(36)	Robert Wood Johnson Medical School, USA	"All had demonstrated serious attempts at weight loss in diet and behavior modification programs"	4/1985 – 5/1999	Open RYGB, with gastric pouch volumes estimated at 20 ±5 mL
Rand (1994)(37)	North Florida Regional Medical Center, USA	Not reported	1/1979 – 12/1990	Open RYGB in 30 patients and open VBG in 4 patients. For RYGB, pouch size range from less than 50 mL to 70 mL.
Studies of Vertical Banded Gastroplasty (VBG)				
Barnett (2005)[a(65)]	University of Minnesota School of Medicine, USA	"All patients were considered eligible for bariatric surgery according to the National Institutes of Health adult criteria"	1978 – 2001	Open VBG
Greenstein (1995)(81)	Mount Sinai School of Medicine CUNY, USA	Not reported	3/1982 – 6/1994	Open Mason VBG
Mason (1995)(82)	University of Iowa College of Medicine, USA	Not reported	1980 – 1994	Open Mason VBG, pouch size average 17.3 mL, range 9-40 mL. The band was a 7 x 1.5 cm Marlex mesh

Study	Location	Prior non-surgical attempts at weight loss	Dates of surgery	Procedural details
Studies of Combined VBG-RYGB				
Capella (2003)(83)	Hackensack University Medical Center, USA	All patients had attempted several weight-reducing regimes that included medically supervised diets, exercise, behavior modification, commercial diets, psychological interventions, and pharmacological agents.	5/1990 – 1/2001	Combined VBG-RYGB

[a] The study by Barnett reported data on both RYGB and VBG, thus it is listed twice.

SAGB - Swedish Adjustable Gastric Band

Table 20. Characteristics of Patients in Included Studies

Study	N	Mean age in years (range)	% female	Mean BMI in kg/m² (SD and range)	Race	Number of patients with specific medical comorbities before surgery[d]						
						Diabetes	Hypertension	Dyslipidemia	Sleep apnea	Asthma	GERD	Musculoskeletal
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)												
Nadler (2007)(61)	53	15.9 (13 - 17)	77% (41/53)	47.6 (SD: 6.7; Range NR)	81% white, 13% Hispanic, 6% black	NR	NR	NR	NR	NR	NR	NR
Yitzhak (2006)(67)	60	16 (9 - 18)	70% (42/60)	43 (SD: NR; Range 35 to 61)	NR	2	3	NR	10	3	NR	NR
Silberhumer (2006)(68,69)	50	17.1 (9 - 19)	62% (31/50)	45.2 (SD: 7.6; Range 32.5 to 76.6)	NR	5	12	4	NR	3	1	8
Angrisani (2005)(70)	58	17.96 (15 - 19)	81% (47/58)	46.1 (SD: 6.31; Range 34.9 to 69.25)	NR	8	8	6	10	NR	NR	12
Fielding (2005)(71-73)	41	15.6 (12 - 19)	73% (30/41)	42.4 (SD: 8.2; Range 31 to 71)	NR	2	2	NR	1	NR	NR	1
Horgan (2005)(74)	4	17.8[a] (17-19)	50% (2/4)	50.5[a] (SD: 8.8[a]; Range 40 to 61)	NR	NR	NR	NR	NR	NR	NR	2
Abu-Abeid (2003)(75)	11	15.7 (11 - 17)	73% (8/11)	46.6 (SD: 5.1[a]; Range 38 to 56.6)	NR	NR	NR	3	NR	NR	NR	NR

Study	N	Mean age in years (range)	% female	Mean BMI in kg/m² (SD and range)	Race	Number of patients with specific medical comorbities before surgery[d]						
						Diabetes	Hypertension	Dyslipidemia	Sleep apnea	Asthma	GERD	Musculoskeletal
Studies of Roux-en-Y Gastric Bypass (RYGB)												
Collins (2007)(76,77)	11	16.5 (15-18)	64% (7/11)	50.5 (SD: 2; Range 42 to 66)	NR	6	6	7	2	4	1	8
Lawson (2006)(66,78-80)	35	17.57 (13 - 21)	66% (23/35)	56.5 (SD: 10.1; Range 41.9 to 95.5)	90% white	NR	NR	NR	10[e]	NR	NR	NR
Barnett (2005)[c](65)	14	15.7 (13 - 17)	57% (8/14)	51 (SD: 9; Range NR)	NR	1	5	NR	2	3	NR	3
Sugerman (2003)(35)	33	16 (12.4 - 17.9)	58% (19/33)	52 (SD: 11; Range 38 to 91)	81% white, 19% black	2[b]	11[b]	NR	6	NR	5	11
Strauss (2001)(36)	10	16.2[a] (15 - 17)	70% (7/10)	53.6[a] (SD: 10.2[a]; Range 41.4 to 70.5)	NR	NR	3	NR	2	NR	NR	1
Rand (1994)(37)	34	17 (11 - 19)	79% (27/34)	47 (SD: 7; Range 38 to 66)	NR	NR	NR	NR	NR	NR	NR	NR
Studies of Vertical Banded Gastroplasty (VBG)												
Barnett (2005)[c](65)	14	15.7 (13 - 17)	57% (8/14)	60 (SD: 20; Range NR)	NR	1	5	NR	2	3	NR	3
Greenstein (1995)(81)	14	17 (13 - 21)	79% (11/14)	47.8[a] (SD: 7.2[a]; Range 41 to 60)	NR	NR	2	NR	1	NR	NR	NR
Mason (1995)(82)	47	18.1 (14 - 20)	68% (32/47)	48.4 (SD: 6.92; Range NR)	NR	NR	NR	NR	NR	NR	NR	NR

Study	N	Mean age in years (range)	% female	Mean BMI in kg/m² (SD and range)	Race	Number of patients with specific medical comorbities before surgery[d]						
						Diabetes	Hypertension	Dyslipidemia	Sleep apnea	Asthma	GERD	Musculoskeletal
Studies of Combined VBG-RYGB												
Capella (2003)(83)	19	15.6[a] (13 - 17)	63% (12/19)	49 (SD: 5.7[a]; Range 38 to 67)	NR	2	3	3	3	NR	NR	NR

GERD Gastroesophageal reflux disease
NR – Information not reported

[a] Calculated by ECRI based on reported information

[b] Sugerman reported inconsistent numbers for the number of patients who had diabetes and/or hypertension at baseline. We used the numbers reported in the results section because they served the basis for comorbidity outcomes.

[c] The study by Barnett reported data on both RYGB and VBG, thus it is listed twice.

[d] Additional comorbidities before surgery included:
Silberhumer (2006): Cholecystolithiasis 3;
Angrisani (2005): Anxiety/depression 1, amenorrhea 4
Horgan (2005): Heartburn without GERD: 2
Abu-Abeid (2003): Cholecystolithiasis 1
Collins (2007): Insulin resistance 1, fatty liver/steatosis 5, hepatomagaly 1, depression 4, hypothyroidism 2, migraines 1, polycystic ovary syndrome 3, anemia 2, gynecomastia 1
Barnett (2005): Attention deficit disorder 5, depression 1, hypothyroidism 1
Sugerman (2003): Psuedotumor cerebri 2, polycystic ovary syndrome 1
Strauss (2001): Hypoventilation 1, dyspnea 1

[e] Sleep apnea reported by a secondary publication.(78)

Table 21. Study Quality Assessments

Study	Prospective?	Consecutive?	Not funded by a direct financial interest?	≥85% completion?	≥85% completion?	≥85% completion?	≥85% completion?	≥85% completion?	≥85% completion?	≥85% completion?	≥85% completion?	≥85% completion?	≥85% completion?	Quality category (s)
	All outcomes	All outcomes	All outcomes	Longest follow-up BMI	1-year BMI	2-year BMI	three-year BMI	4-year BMI	5-year BMI	Comorbidities	Quality of life	Adverse events	Patient characteristics to predict outcomes	
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)														
Nadler (2007)(61)	Yes	Yes	NR	NA	NA	NA	NA	NA	NA	NA	NA	Yes	NA	Moderate
Yitzhak (2006)(67)	No	Yes	NR	Yes	NA	NA	NA	NA	NA	Yes	NA	Yes	NA	Moderate
Silberhumer (2006)(68,69)	NR	Yes	NR	Yes	NA	NA	NA	NA	NA	Yes	Yes	Yes	NA	Moderate
Angrisani (2005)(70)	Yes	Yes	NR	No	Yes	NA	No	NA	NA	NA	NA	Yes	NA	Moderate
Fielding (2005)(71-73)	Yes	Yes	NR	Yes	Yes	No	NA	NA	NA	Yes	NA	Yes	Yes	Moderate
Horgan (2005)(74)	No	Yes	NR	NA	NA	NA	NA	NA	NA	Yes	NA	Yes	NA	Moderate
Abu-Abeid (2003)(75)	No	NR	NR	Yes	Yes	No	NA	NA	NA	NA	NA	Yes	Yes	Low for all outcomes except for 2-year BMI, which was Very Low

Study	All outcomes Prospective?	All outcomes Consecutive?	All outcomes Not funded by a direct financial interest?	Longest follow-up BMI ≥85% completion?	1-year BMI ≥85% completion?	2-year BMI ≥85% completion?	three-year BMI ≥85% completion?	4-year BMI ≥85% completion?	5-year BMI ≥85% completion?	Comorbidities ≥85% completion?	Quality of life ≥85% completion?	Adverse events ≥85% completion?	Patient characteristics to predict outcomes ≥85% completion?	Quality category (s)
Studies of Roux-en-Y Gastric Bypass (RYGB)														
Collins (2007)(76,77)	No	Yes	NR	No	NA	NA	NA	NA	NA	Yes	NA	Yes	NA	Moderate for all outcomes except for longest follow-up BMI, which was Low
Lawson (2006)(66,78-80)	No	Yes	No	No	No	NA	NA	NA	NA	Yes	NA	Yes	NA	Moderate for all outcomes except for longest follow-up BMI and 1-year BMI, which were Low
Barnett (2005)[a](65)	No	Yes	NR	NA	NA	NA	NA	NA	NA	NA	NA	Yes	NA	Moderate
Sugerman (2003)(35)	No	Yes	NR	Yes	Yes	NA	NA	NA	No	Yes	NA	Yes	NA	Moderate for all outcomes except for 5-year BMI, which was Low
Strauss (2001)(36)	No	Yes	NR	Yes	Yes	No	No	No	NA	Yes	NA	Yes	Yes	Moderate for all outcomes except for 2-year BMI, three-year BMI, and 4-year BMI, which were Low
Rand (1994)(37)	No	No	NR	Yes	NA	NA	NA	NA	NA	NA	NA	Yes	NA	Low

Study	All outcomes Prospective?	All outcomes Consecutive?	All outcomes Not funded by a direct financial interest?	Longest follow-up BMI ≥85% completion?	1-year BMI ≥85% completion?	2-year BMI ≥85% completion?	three-year BMI ≥85% completion?	4-year BMI ≥85% completion?	5-year BMI ≥85% completion?	Comorbidities ≥85% completion?	Quality of life ≥85% completion?	Adverse events ≥85% completion?	Patient characteristics to predict outcomes ≥85% completion?	Quality category (s)
Studies of Vertical Banded Gastroplasty (VBG)														
Barnett (2005)[a](65)	No	Yes	NR	NA	NA	NA	NA	NA	NA	NA	NA	Yes	NA	Moderate
Greenstein (1995)(81)	No	No	NR	Yes	NA	NA	NA	NA	NA	NA	NA	Yes	Yes	Low
Mason (1995)(82)	No	No	NR	No	NA	NA	NA	NA	No	NA	NA	Yes	NA	Low for all outcomes except for longest follow-up BMI and 5-year BMI, which were Very Low
Studies of Combined VBG-RYGB														
Capella (2003)(83)	No	Yes	NR	No	NA	NA	No	No	NA	NA	NA	Yes	No	Moderate for all outcomes except for longest follow-up BMI, three-year BMI, 4-year BMI, and individual data for Key Question 5, which were Low

[a] The study by Barnett reported data on both RYGB and VBG, thus it is listed twice.

NA - Not applicable because either the study did not report the pertinent data, or the reported data did not meet inclusion criteria

Table 22. Data for Key Question 1 (BMI) for Longest Followup

Study	N	Pre-surgical BMI in kg/m² (SD)	Length of followup (years)	Post-surgical BMI in kg/m² at longest follow-up (SD)	BMI units (kg/m²) lost (95% CI)
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)					
Yitzhak (2006)(67)	60	43 (SD: 7.4)	3.3 (range 2.1 to 5.4)	30 (SD: 8.4) [a,b]	-13 (-14.8 to -11.2)
Silberhumer (2006)(68,69)	50	45.2 (SD: 7.6)	2.9 (range 0.3 to 7.2)	32.6 (SD: 6.8)[b]	-12.6 (-14.4 to -10.8)
Angrisani (2005)(70)	37	46.1 (SD: 6.31)	3	37.8 (SD: 11.27) [b]	-8.3 (-11.2 to -5.4)
Fielding (2005)[c](71-73)	17	43.1 (SD: 9.6)	1.7 (range 1 to 2)	30.2 (SD: 7.3)	-12.9 (-15.5 to -10.3)
Abu-Abeid (2003)(75)	11	46.5 (SD: 5.1)	1.9 (range 1 to 3)	32.5 (SD: 4)	-14 (-16.5 to -11.5)
Studies of Roux-en-Y Gastric Bypass (RYGB)					
Collins (2007)[d](76,77)	3	52 (SD: 12.1)	1.8 (range 1.7 to 1.8)	28 (SD: 8.7) [b]	-24 (-35.1 to -12.9)
Lawson (2006)(66,78-80)	30	56.5 (SD: 10.1)	1	35.8 (SD: 6.9) [b]	-20.7 (-23.6 to -17.8)
Sugerman (2003)(35)	24	52 (SD: 11)	5	33 (SD: 11) [b]	-19 (-22.9 to -15.1)
Strauss (2001)(36)	9	52 (SD: 9.4)	6.3 (1 to 13)	35.2 (SD: 12.4)	-16.8 (-24.3 to -9.3)
Rand (1994)(37)	34	47 (SD: 7)	6 (range 2 to 13)	32 (SD: 7) [b]	-15 (-17.1 to -12.9)

Study	N	Pre-surgical BMI in kg/m² (SD)	Length of followup (years)	Post-surgical BMI in kg/m² at longest follow-up (SD)	BMI units (kg/m²) lost (95% CI)
Studies of Vertical Banded Gastroplasty (VBG)					
Greenstein (1995)(81)	14	47.8 (SD: 7.2)	5.6 (range 1 to 10)	32.5 (SD: 8.9)	-15.3 (-20.4 to -10.2)
Studies of Combined VBG-RYGB					
Capella (2003)(83)	15	46.7 (SD: 5.7)	5.5 (range 1 to 10)	28.9 (SD: 5.5)	-17.8 (-20.4 to -15.2)

[a] Imputed SD based on other studies
[b] Imputed pre-post correlation based on other studies
[c] Data for a secondary publication(72) were used because the weight data from the primary publication did not include at least 50% of patients with 1+ years followup
[d] Data for a secondary publication(77) were used because the weight data from the primary publication did not include at least 50% of patients with 1+ years followup

CI – Confidence interval

Note: Four studies reported BMI data that did not meet inclusion criteria, for the following reasons. The study by Nadler did not report 1+ year data for at least 50% of patients. The study by Hogan did not report 1+ year data for at least three patients. The study by Barnett did not report the length of follow-up of patients receiving specific procedures. The study by Mason was rated very low quality for BMI data and therefore was excluded from Key Question 1.

Table 23. Data for Key Question 1 (BMI) for Specific Timepoints

Study	N	Pre-surgical Mean BMI in kg/m² (SD)	Mean BMI after surgery									
			One year		Two years		Three years		Four years		Five years	
			N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)												
Yitzhak (2006)(67)	60	43 (SD: 7.4)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Silberhumer (2006)(68,69)	50	45.2 (SD: 7.6)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Angrisani (2005)(70)	37	46.1 (SD: 6.31)	48	35.9 (SD: 8.4)	NR	NR	37	37.8 (SD: 11.27)	NR	NR	NR	NR
Fielding (2005) [a](71-73)	17	43.1 (SD: 9.6)	17	33 (SD: 7)	11	29.5 (SD: 4.8)	NR	NR	NR	NR	NR	NR
Abu-Abeid (2003)(75)	11	46.5 (SD: 5.1)	11	34 (SD: 3.4)	NI	NI	NR	NR	NR	NR	NR	NR
Studies of Roux-en-Y Gastric Bypass (RYGB)												
Collins[b] (2007)(76,77)	3	52 (SD: 12.1)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Lawson (2006)(66,78-80)	30	56.5 (SD: 10.1)	30	35.8 (SD: 6.9)	NR	NR	NR	NR	NR	NR	NR	NR
Sugerman (2003)(35)	24	52 (SD: 11)	32	36 (SD: 10)	NR	NR	NR	NR	NR	NR	24	33 (SD: 11)
Strauss (2001)(36)	9	52 (SD: 9.4)	9	34 (SD: 7.7)	7	31.2 (SD: 7.8)	7	32.2 (SD: 9.8)	5	35.2 (SD: 14.7)	NR	NR
Rand (1994)(37)	34	47 (SD: 7)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Study	N	Pre-surgical Mean BMI in kg/m² (SD)	Mean BMI after surgery									
			One year		Two years		Three years		Four years		Five years	
			N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)
Studies of Vertical Banded Gastroplasty (VBG)												
Greenstein (1995)(81)	14	47.8 (SD: 7.2)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Studies of Combined VBG-RYGB												
Capella (2003)(83)	15	46.7 (SD: 5.7)	NR	NR	NR	NR	10	26.5 (SD: 2.4)	9	28.5 (SD: 6.5)	NR	NR

BMI – Body mass index
N – Number of patients
NI – Data not included because of very low quality for this timepoint
NR – Not reported
SD – Standard deviation

[a] Data for a secondary publication(72) were used because the weight data from the primary publication did not include at least 50% of patients with 1+ years followup
[b] Data for a secondary publication(77) were used because the weight data from the primary publication did not include at least 50% of patients with 1+ years followup

Note: Four studies reported BMI data that did not meet inclusion criteria, for the following reasons. The study by Nadler did not report 1+ year data for at least 50% of patients. The study by Hogan did not report 1+ year data for at least three patients. The study by Barnett did not report the length of follow-up of patients receiving specific procedures. The study by Mason was very low quality for BMI data and therefore was excluded from Key Question 1.

Table 24. Data for Key Question 2 on Resolution of Comorbidities

Study		Diabetes	Hypertension	Dyslipidemia[b]	Sleep Apnea	Asthma	GERD	Musculoskeletal[c]	Notes
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)									
Yitzhak (2006)(67)	Baseline N	2	3	-	10	3	-	-	-
	Resolved %	100% (2/2)	100% (3/3)	-	100% (10/10)	100% (3/3)	-	-	-
Silberhumer (2006)(68,69)	Baseline N	5	12	4	-	3	1	8	3 cholelithiasis
	Resolved %	80% (4/5)	50% (6/12)	100% (4/4)	-	100% (3/3)	100% (1/1)	38% (3/8)	100% resolution for cholelithiasis. Cases that improved but not resolved included one for diabetes, six for hypertension, and five for musculoskeletal problems.
Fielding (2005)(71-73)	Baseline N	2	2	-	1	-	-	1	-
	Resolved %	100% (2/2)	100% (2/2)	-	100% (1/1)	-	-	100% (1/1)	-
Horgan (2005)(74)	Baseline N	-	-	-	-	-	-	2	Also, two patients had heartburn without GERD.
	Resolved %	-	-	-	-	-	-	100% (2/2)	Heartburn outcomes not reported
Abu-Abeid (2003)(75)	Baseline N	-	-	3	-	-	-	-	1 Heart failure and pulmonary hypertension; 3 recurrent boil, 2 skin rashes; 7 stretch marks; 2 amenorrhea;1 cholelithiasis; offensive body odor and unpleasant appearance.
	Resolved %	-	-	67% (2/3)	-	-	-	-	Heart failure, pulmonary hypertension, and amenorrhea resolved; others not reported

Studies of Roux-en-Y Gastric Bypass (RYGB)									
Collins (2007)(76,77)	Baseline N	6	6	7	2	4	1	8	4 depression/anxiety; 5 fatty liver/steatosis; 1 hepatomegaly; 2 hypothyroidism; 1 migraines; 3 polycystic ovarian syndrome; 2 iron deficiency anemia; 1 gynecomastia; and 1 insulin resistance
	Resolved %	50% (3/6)	50% (3/6)	NR	0% (0/2)	NR	NR	NR	Cases that improved but not resolved included 3 for hypertension, two for diabetes, and two for sleep apnea cases. 2 out of 3 polycystic ovarian syndrome improved; other comorbidities not reported
Lawson (2006)(66,78-80)	Baseline N	-	-	-	10[a]	-	-	-	-
	Resolved %	-	-	See notes	100% (10/10)	-	-	-	For dyslipidemia, study did not report resolution or improvement rates, but instead reported overall statistically significant postoperative improvements in triglyceride, total cholesterol, fasting blood glucose, and fasting insulin.
Sugerman (2003)(35)	Baseline N	2	11	-	6	-	5	11	3 pseudotumor cerebri; 3 polycystic ovarian syndrome
	Resolved %	100% (2/2)	82% (9/11)	-	100% (6/6)	-	60% (3/5)	36% (4/11)	100% resolution in the 3 cases of pseudotumor cerebri and also in the 3 cases of polycystic ovarian syndrome
Strauss (2001)(36)	Baseline N	-	3	-	2	-	-	1	1 progressive dyspnea on exertion; obesity-hypoventilation syndrome1; 1 refusing to attend school because of teasing
	Resolved %	-	100% (3/3)	-	100% (2/2)	-	-	NR	The patient reentered school; other comorbidities not reported
Studies of Vertical Banded Gastroplasy (VBG)									
Greenstein (1995)(81)	Baseline N	-	2	-	1	-	-	-	-
	Resolved %	-	NR	-	100% (1/1)	-	-	-	-

[a] Sleep apnea outcomes reported by a secondary publication.(78)
[b] Dyslipidemia includes those reported as dyslipidemia, hyperglyceridemia and hypercholesterolemia
[c] Reported musculoskeletal conditions included those reported as orthopedic problems, osteoarthropathy, joint and musculoskeletal complaints, degenerative joint disease. back pain, arthralgia, and vertebra fractures

GERD Gastroesophageal reflux disease
NR or – indicate that the study did not report any patient outcomes for this comorbidity

Table 25. Data for Key Question 2 on Quality of Life

Study	N	Length of follow-up	Instrument[a]	QOL score before surgery	QOL score before surgery	P value[b]
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)						
Silberhumer(2006)(68,69)	50	Mean 34.7 months, SD 17.5, Range 3.6 to 85.4 months	Moorehead-Ardelt	0.8 (SD 0.3)	2.1 (SD 0.8)	P <0.0001

[a] Scores on the Moorehead-Ardelt quality-of-life instrument range from -3 to 3 where 3 represents excellent quality-of-life and -3 represents very poor quality-of-life.(116)
[b] p value calculated by ECRI based on a t-test.

SD –Standard deviation

Note: Four studies reported quality-of-life data that did not meet inclusion criteria for the following reasons: In three studies (Yitzhak, Rand, Greenstein), the quality of life instrument was not previously validated, and only postoperative data were reported. In the fourth study (Collins), only postoperative data were reported. The Silberhumer study also reported BAROS data, but these data were not included because BAROS is only used after surgery.

Table 26. Data for Key Question 3 on Reported Adverse Events for LAGB[a]

Study	Number of patients	Band used	Dates of surgery	Follow-up time	Reported adverse events (case number)	Treatments for adverse events
Nadler (2007)(61)	53	LAP-BAND	9/2001-2/2006	At 6 (n = 33), 12 (n = 18), 18 (n = 6), and 24 (n = 2) months	Band slippage (2), hiatal hernia (2); wound infection (1), nephrolithiasis and cholelithiasis (1), gastroesophageal reflux (1), mild hair loss (5), iron deficiency (4)	Laparoscopic band reposition, laparoscopic hiatal hernia repair, medical therapy for GERD, and nutritional counseling and supplementations
Yitzhak (2006)(67)	60	SAGB[b]	2000-2006	39.5 (25-65) months	Band slippage (8)	Band reposition for 6 patients and band removal for 2 patients
Silberhumer (2006)(68,69)	50	SAGB & LAP-BAND	1998-2004	34.7 (3.6-85.4) months	Dislocated port (1)	Not reported
Angrisani (2005)(70)	58	LAP-BAND	1/1996-12/2003	At 1, 3, 5, and 7 years	Band slippage (1), gastric pouch dilatation (2), intragastric migrations (3), psychological intolerance of band (2), Conversion to laparoscopic GB in 2 years (1), biliopancreatic diversion with gastric preservation and band left in situ (2)	Band reposition for band slippage and gastric pouch dilations, band removal for intragastric migration and psychological intolerance
Fielding (2005)(71-73)	41	LAP-BAND	1998-2003	33.8 (1-70) months	Band slippage (1), tubing crack (1)	Laparoscopic band reposition for band slippage and exploratory procedure to repair the tubing crack
Horgan (2005)(74)	4	LAP-BAND	2001-2003	13.3 (4-30) months	Cholecystitis (1)	Outpatient laparoscopic cholecystectomy
Abu-Abeid (2003)(75)	11	LAP-BAND	Not reported	23 (6-36) months	Iron deficiencies (4)	Iron supplementation

[a] No perioperative death attributable to the surgical procedure was reported in the studies.

[b] SAGB - Swedish Adjustable Gastric Band

Table 27. Data for Key Question 3 on Reported Adverse Events for RYGB[a]

Study	Number of patients	Approach	Date of surgery	Follow-up time	Reported adverse events (case number)	Treatments for adverse events
Collins (2007)(76,77)	11	Laparoscopic	1999 - 6/2005	11.5 (3-32) months	Immediate postoperative bleeding (1), marginal ulcer (2)	Laparoscopic re-exploration for postoperative bleeding and use of proton pump inhibitor for marginal ulcers
Lawson (2006)(66,78,79)	39	Laparoscopic (n = 36) and open (n = 3)	5/2001-10/2003	Within 1 year	There is neither perioperative death nor severe surgical complications. Two patients had at least one of the following: death[b] and severe beriberi. Four patients had at least one of the following: persistent iron deficiency anemia, peripheral neuropathy secondary to vitamin deficiency, reoperation (for staple line leak, obstruction, or gastrostomy revision), shock, and internal hernia. Nine patients had at least one of the following: endoscopy (for melena, suspected obstruction, or stricture), food obstruction, wound infection, anastomotic stricture/gastrojejunostomy stricture, nausea, dumping syndrome secondary to overeating, diarrhea, dehydration, mild beriberi, hypokalemia, deep vein thrombosis.	Not reported
Barnett (2005)(65)	15 procedures on 14 patients (including 5 RYGBs)	Open	1978 – 2001	6 years (9 month.-21.75 years)	The following were linked to the 5 RYGB cases: Dumping syndrome (2); hypoglycemia (1)	Both dumping syndrome cases were resolved within 1 year without further surgical intervention. The hypoglycemia case was treated medically without difficulty.
Sugerman (2003)(35)	33 (1 HGP, 2 VBG,17standard GBPs, 10 LL-GBPs, 3 D-GBPs) [c]	Open (n = 31) and laparoscopic (on 2 standard GBPs)	1981 – 1/2002	2 weeks, 3, 6, 12 , 18 months, and yarely thereafter	Early complications: pulmonary embolism (1), major wound infection (1), minor wound infection (4), stomal stenoses (3), marginal ulcer (4) Late complications: small bowel obstruction (1), incisional hernia (6) Conversion from D-GBP to standard gastric bypass due to severe protein-calorie malnutrition (1)	Endoscopic dilation for stomal stenoses, medical treatments for marginal ulcers, adhesiolysis for small bowel obstruction, and herniorrhaphy with polypropylene for incisional hernias

Study	Number of patients	Approach	Date of surgery	Follow-up time	Reported adverse events (case number)	Treatments for adverse events
Strauss (2001)(36)	10	Open	4/1985 – 5/1999	Follow-up >1 year was present in 9 patients	No early complications Late complications: incisional hernia (1), symptomatic cholelithiasis (2), protein-calorie malnutrition and micronutrient deficiency (1), and small bowel obstruction caused by adhesion and internal hernia (1), minor nutritional complications include iron deficiency anemia (5), transient folic acid deficiency (3)	Laparoscopic cholecystectomy for symptomatic cholelithiasis, TPN and Abx for protein-calorie malnutrition, operative correction for small bowel obstruction, operative repair of incisional hernia, vitamin and mineral supplementation for iron and folic acid deficiencies
Rand (1994)(37)	34 (30 RYGBs and 4VBGs)	Open	1/1979 – 12/1990	6 years	There were no major postoperative complications.	Revisional surgery to reduce size of the pouch for better weight loss results (3 performed, 2 scheduled), cholecystectomy (4), and abdominal panniculectomy (1)

[a] No perioperative death attributable to the surgical procedure was reported in the studies.

[b] The patient initially presented with hypercholesterolemia, hyperinsulinemia, hypertension, sleep apnea, and degenerative joint disease at a BMI of 80 kg/m^2 and weight of 630 lb. After an initial uncomplicated 3-month postoperative course, the patient developed severe infectious colitis because of Clostridium difficile. This illness was contracted while undergoing inpatient rehabilitation of his weight-related lower extremity osteoarthropathy in a long-term care facility distant from the bariatric center. Severe diarrhea and extended period of profound hypovolemia associated with the colitis resulted in multiorgan failure and subsequent death 9 months after RYGB.

[c] HGP—Horizontal gastroplasty, VBG—Vertical banded gastroplasties, GPS—Gastric bypass, LL-GBP—Long-lime gastric bypass, D-GBP—Distal gastric bypass

Table 28. Data for Key Question 3 on Reported Adverse Events for Other Bariatric Surgeries

Study	Number of patients	Procedure	Date of surgery	Follow-up time	Reported adverse events (case number)	Treatments for adverse events
Greenstein (1995)(81)	18	VBG	3/1982 – 6/1994	3-120 months	Major morbidities included recurrent gastric ulceration in two female patients who were heavy cigarette smokers.	Not reported.
Mason (1995)(82)	47	VBG	1980 – 1994	Up to 5 year (n = 35) or 10 years (n = 19)	No operation-related deaths; no leaks or instances of peritonitis; no pneumonia nor wound infections 3 late revisions for unsatisfactory weight loss results (2 due to enlarged pouches and 1 due to disrupted staple line)	Surgical revisions for enlarged pouches and disrupted staple line
Capella (2003)(83)	19	VBG-RYGB	5/1990 – 1/2001	5.5 (1-10) years	No postoperative mortality or serious morbidity.	Two revisions for gastro-gastric fistula, one cholecystectomy, one recurrent marginal ulcer requiring antacids, three plastic surgeries for excess skins

[a] No perioperative death attributable to the surgical procedure was reported in the studies.

[b] The study was also reported in Table 17 because it covered more than one type of bariatric surgery.

[c] HGP—Horizontal gastroplasty, VBG—Vertical banded gastroplasties, GPS—Gastric bypass, LL-GBP—Long-lime gastric bypass, D-GBP—Distal gastric bypass

Figure 18. Age and BMI Change: Individual Patient Data

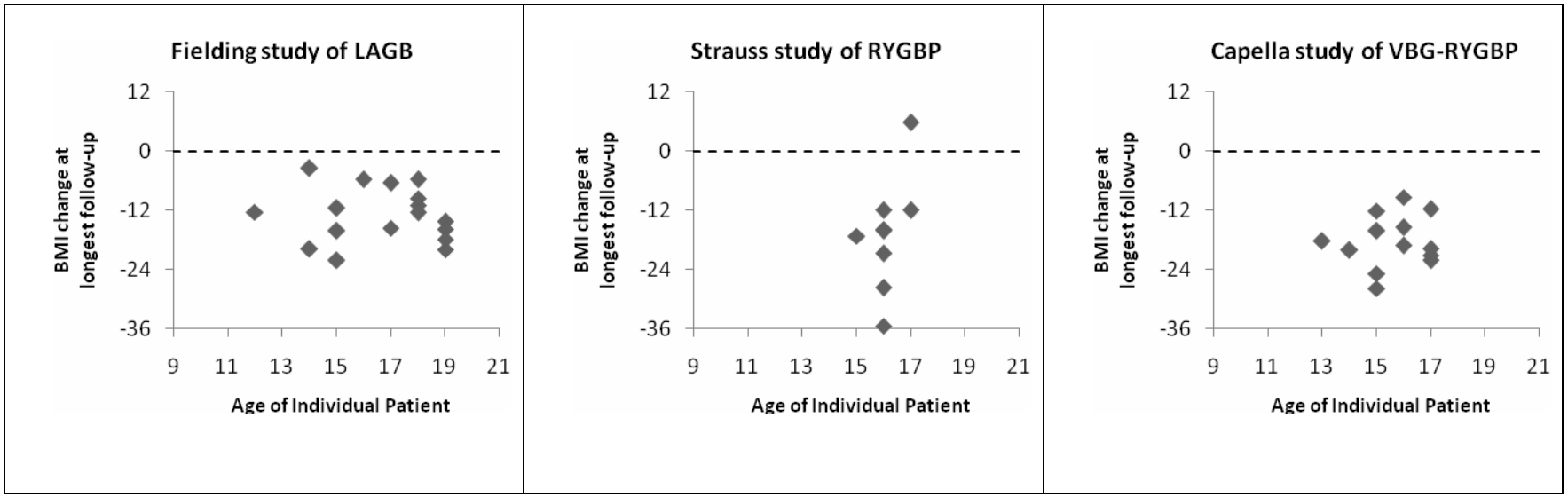


Figure 19. Presurgical BMI and BMI Change: Individual Patient Data

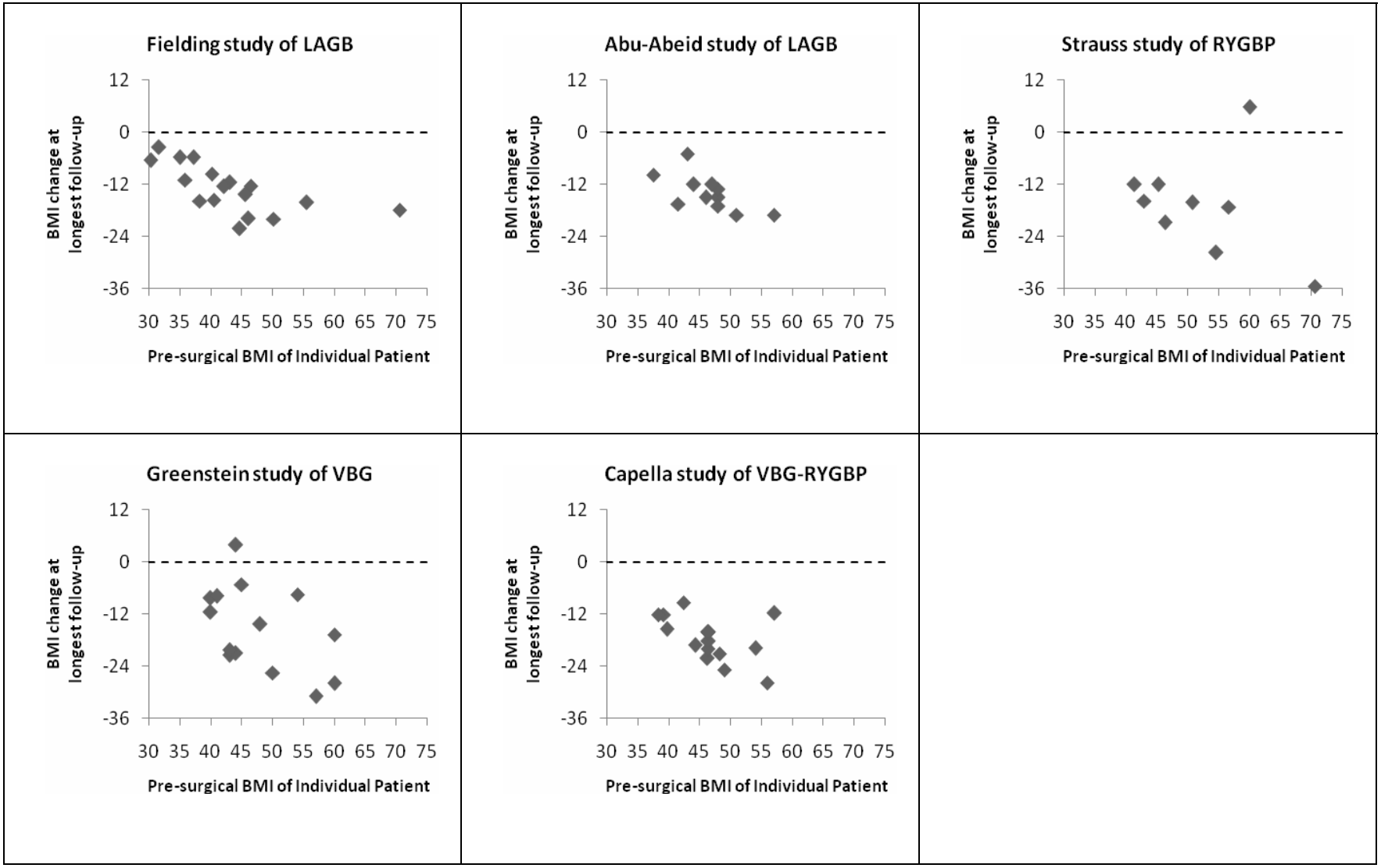


Figure 20. Presurgical BMI Category and BMI Change: Individual Patient Data

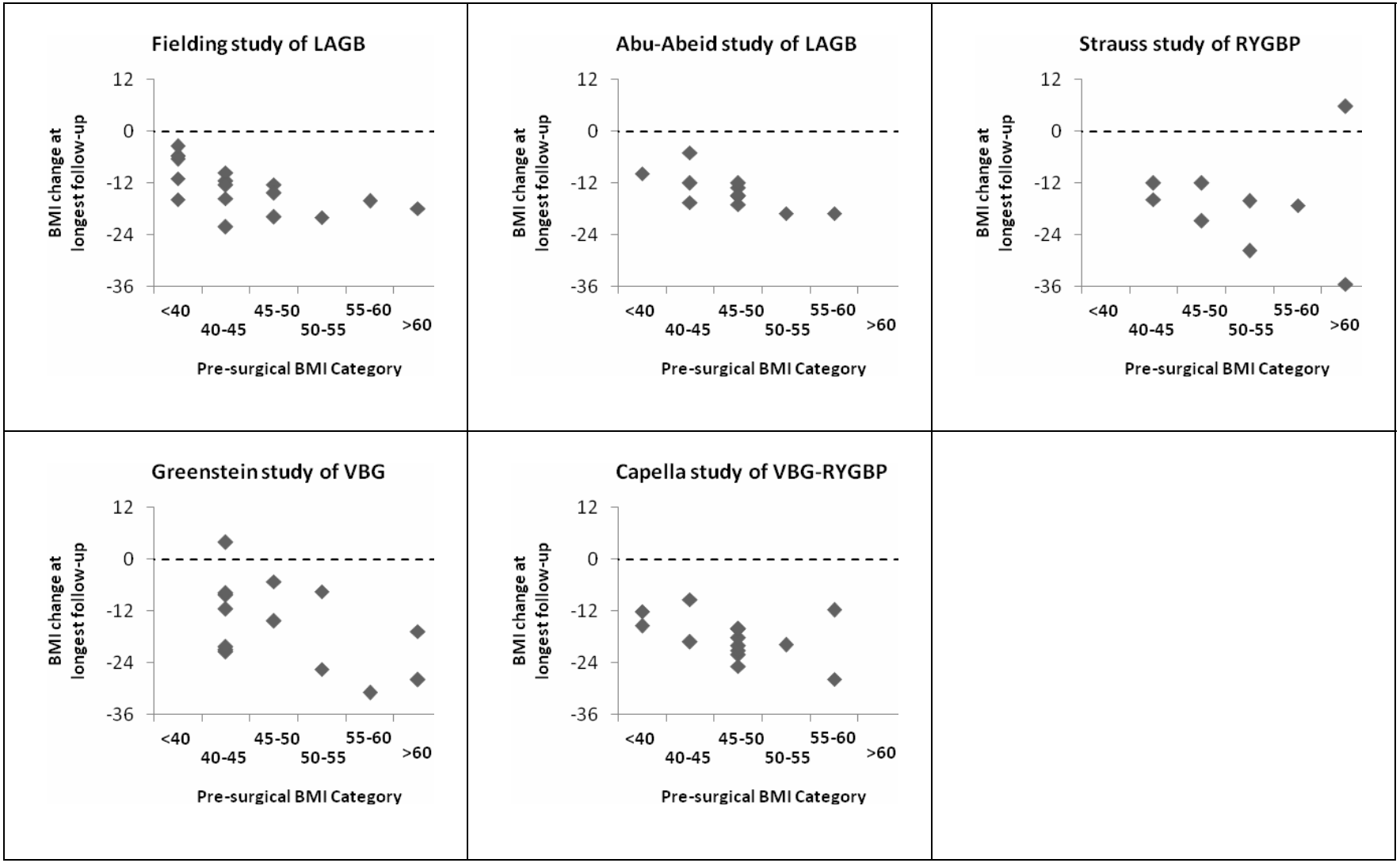


Figure 21. Sex and BMI Change: Individual Patient Data